

*STRATEGIES
FOR THE FUTURE*

THE ROLE OF TECHNOLOGY IN REDUCING HEALTH CARE COSTS

OCTOBER 1996



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foreword

OBJECTIVE

Technology innovation has resulted in improved productivity and lower costs in many sectors of the US economy. In the medical field, however, technology advances have often been viewed as a major cost driver. The objective of this project has been to identify those technologies and technology-related policies with the potential for reducing health care costs while maintaining or improving quality. This document details eight technology and policy roadmaps that provide guidance for future development and introduction of cost-effective technologies and technology-related policies for the US health care delivery system.

Roadmaps are strategic plans for the development and introduction of technologies and policies into an essential economic or system area to maximize the valued outputs of the system. Outputs can be cost, quality, performance, or any other featured system product.

Roadmaps provide important planning guidelines for the development and introduction of technologies and technology-related policies. They identify a common vision for timely solutions of fundamental system problems that are “needs” driven rather than “solutions” driven. Each roadmap is designed to be a working document and may be updated as required.

In addition, roadmaps provide consensus in the development and introduction of innovative technologies by:

- Reducing duplication of essential research, development and application activities among stakeholders
- Addressing technology challenges that may be too expensive or too risky for a single organization to solve
- Providing a comprehensive view of the broader system problems

THE BIOMEDICAL TECHNOLOGY ROADMAP DEVELOPMENT PROCESS

Because of the complexity of the issues facing the US health care delivery system, a gaming approach was selected as the mechanism to build consensus and to develop roadmaps establishing technology's role in meeting care delivery needs. The Biomedical Prosperity Game was the initial event in this approach to explore complex issues facing the US health care system. The Technology Roadmap Workshop was held approximately six months later. Prosperity Games are interactive simulations that explore complex issues in a variety of economic, political and social arenas — they are not computer games. The simulations are high-level exercises of discretion, judgment, planning and negotiating skills.

BIOMEDICAL PROSPERITY GAME®

The Biomedical Prosperity Game®, conducted on November 1-3, 1995, in Albuquerque, NM, brought together various stakeholders representing more than 40 organizations with expertise in the broad spectrum of health care technologies and policies. The Game provided an environment to create alternative futures addressing these issues by providing:

- A format for prioritizing issues amidst an environment of competing self interests
- A process for addressing high-level solutions to very large problems that may not be solvable by other methods
- A unique environment for fostering collaboration and managing conflict

This document presents eight roadmaps designed to guide the development of the future health care system

The Biomedical Prosperity Game was an initial vehicle for roadmap development

A wide range of health care stakeholders participated in the Game

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Participants were able to gain understanding of opportunities and obstacles facing health care

In addition, the Game provided participants with an understanding of some of the obstacles and opportunities associated with current and proposed technologies and technology-related policy. For example, problems and opportunities faced by doctors and other health care providers, patients, technology developers, the military, regulators, legislators, insurance agencies, lawyers, and other stakeholders in the biomedical engineering field were explored.

The Game proved to be an invaluable learning experience that produced a prioritized list of technology and technology-related policy areas. These areas are identified in the “The Biomedical Technology Roadmap Workshop” section that follows.

Overall, the players expressed a strong interest in emphasizing the general health and health care information areas for future technology and technology-related policy development.

The future health care system infrastructure should be able to address all levels of health care complexity

The players’ general consensus was that the future health and health care information infrastructure must support systems capable of handling all measures of care complexity while maintaining flexibility, responsiveness and quality. Several comments pointed out the current imbalance of health and health care information: doctors are increasingly burdened with a deluge of information while patients have access to relatively little information. In particular, future health information systems were proposed that would allow individuals to proactively participate with care professionals in the improvement of their personal health status.

The principal products of the Biomedical Prosperity Game were eight technology and policy roadmap outlines for the prioritized health care technology areas. These outlines consisted of the vision and objectives; fundamental drivers; and organization infrastructure required for the proper development and introduction of promising health care technologies and technology-related policies. In addition, much of the discussion identifying potential technology and policy solutions to critical health care issues were recorded and cataloged according to the roadmap areas.

BIOMEDICAL TECHNOLOGY ROADMAP WORK GROUPS

Champions and work groups led the development of each roadmap

Following the Prosperity Game, champions were identified and work groups formed to guide the further development of each roadmap outline into a final roadmap product. The work group members consisted of experts in health technology and policy fields related to the individual roadmap areas.

Depending upon the breadth of the technology area, work groups ranged in size from 8 to 26 persons. It should be noted that more than 75 organizations and 150 individuals participated in the overall process. Commitment from this broad spectrum of persons and organizations have helped validate the objectives and details for each roadmap.

In preparation for the Biomedical Technology Roadmap Workshop, each work group expanded their roadmap outline into a draft technology roadmap. Much of this work was done primarily via electronic discussion means.

THE BIOMEDICAL TECHNOLOGY ROADMAP WORKSHOP

A Roadmap Workshop helped advance the details for each roadmap

The Biomedical Technology Roadmap Workshop was held on April 22-24, 1996, in Albuquerque, NM. The Workshop provided an opportunity for the technology roadmap work groups to convene and advance the details for each draft technology roadmap. The Workshop sessions were based upon templates that guided each work group to move from goals to priorities supported by the commitment of the participants. The templates were detailed by the informed discussion of the work group members to ensure that the important issues concerning roadmapping were addressed. In addition, the draft technology roadmaps

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supplemented the templates for facilitating discussion during the sessions. At the conclusion of the Workshop, each work group reported clarified definitions for high-leverage goals; objectives; drivers and requirements; and priorities in the context of the evolving health care infrastructure.

Goals refined at the Workshop are indicated for each of the roadmap areas as follows:

- **Advanced Telemedicine**
Goal: Provide appropriate and efficient care service to the point of need.
- **Health and Health Care Informatics**
Goal: Establish a component integration strategy for health and health care information systems.
- **Information and Network Surety**
Goal: Health information should be accessible over public networks from multiple vendor platforms, with appropriate protection for individual privacy and data integrity. Access should be controlled through effective authentication and effective audit processes with appropriate sanctions to provide care service cost savings and improved health care.
- **Integrated Predictive Diagnostics**
Goal: Develop model-based health monitoring and prediction capabilities which enable tailored intervention for improved medical outcomes.
- **Minimally Invasive Therapy, Imaging, and Energy Delivery Systems**
Goal: Optimize and extend the use of technology to provide the most rapid return to well being possible from an effective therapeutic intervention.
- **Performance Measurement and Outcomes Research**
Goal: Develop and implement a dynamic, valid, reliable, comprehensive and cost-effective health care delivery monitoring system.
- **Preventive Medicine and Incentive Programs**
Goal: Build healthy communities by creating prevention paradigms incentivizing healthy behaviors (individual, community, business, and government) and optimizing economic efficiency and productivity, health status, and quality of life.
- **Rehabilitative Science and Assistive Technologies**
Goal: Maximize integration of the person with disability into society by creating and restoring meaningful life roles through innovative rehabilitation sciences and assistive technologies.

f o r e w o r d

Cooperation and support resulted
in an overall plan for the future
US health care technology

CONSORTIA AND WORKING ALLIANCES

Following the Workshop, each work group completed their roadmap by incorporating the recommendations resulting from the Workshop sessions in addition to other expert commentary. In order to assure progress against the goals detailed in the completed strategic plans, these technology and policy roadmaps will now be disseminated to consortia and working alliances committed to the advancement of the nation's health care delivery system. The health care system stakeholders will provide the follow up essential to achieve the goals outlined in the Roadmaps.

FINAL COMMENT

We deeply appreciate the cooperation and support of the cosponsoring organizations in the development of the Technology Roadmaps. Cosponsorship has proved to be an important means for pooling resources to achieve similar goals for lowering the cost while improving the quality of future applications of health care technologies. The list of cosponsors for the overall effort include:

- US Army Medical Research & Materiel Command
- The Koop Foundation, Inc. (KFI)
- Defense Advanced Research Projects Agency (DARPA)
- Massachusetts General Hospital
- Pennsylvania State University Applied Research Laboratory
- Presbyterian Hospital of Dallas
- Sandia National Laboratories

The Roadmaps that follow comprise an overall technology plan for the future US health care delivery system. This plan will allow the country to derive cost-effective, higher-quality, patient-centered benefits from health care technology and technology-related policy developments. A healthy population, achieved by a balanced plan at a rational cost, is a priority for ensuring the future national competitiveness of the nation.

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ADVANCED TELEMEDICINE TECHNOLOGY ROADMAP



Telemedicine has the potential to ameliorate many problems associated with limited access to health services in the United States. Appropriately utilized, telemedicine may reduce the direct and indirect costs of care to patients, providers, and payers. The purpose of this Technology Roadmap is to outline the steps necessary for the establishment of a national telemedicine infrastructure over the next 15 years. While many of the objectives are technological in nature, even more problematic are the policy issues that must be addressed, including deregulation of the telecommunications industry, establishment of coverage and payment policy for telemedicine, and national licensing of physicians and other providers. This document provides a detailed agenda for action that must be undertaken to realize the goal of a ubiquitous, comprehensive, reliable electronic health care network.

DESCRIPTION

Telemedicine can improve the delivery of health care

Telemedicine, the use of telecommunications and information technology to provide health services at a distance, may serve to ameliorate many of the problems endemic to the health care system in the United States. Because the technology is essentially distance insensitive, telemedicine is likely to improve the delivery of care by eliminating inequities in the distribution of providers and specialized services. The accessibility of specialty and subspecialty consultation, the capacity to perform remote monitoring of patients' health status, and the availability of health-related information for both patients and providers stand to improve the quality of care rendered. Appropriately utilized, telemedicine may reduce the direct and indirect costs of care to patients, providers, and payers.

The goals of the Advanced Telemedicine Technology Roadmap are to:

- Establish a strategy for the development, deployment, and use of a wide array of telemedicine technologies
- Identify barriers to full implementation of telemedicine and outline a detailed approach to addressing them

Strategic planning can identify areas that need and will benefit from telemedicine

Strategic planning for telemedicine is of fundamental importance. We need to develop a system for intelligent communication that extends our senses, facilitates our communication, records our activity, and augments our intelligence. This process first should focus on the health and health care needs of individual communities and of demographically and clinically defined subgroups of the population. Following that, it is essential to develop, from the range of technical options available, those that will provide flexible, appropriate, and practical access to services and information. In this way health knowledge and services may be brought directly to those who need them — both patients and providers.

Policy is needed that supports the development of telemedicine

Several factors currently impede the development of telemedicine. Although technological problems are among them, these at least admit relatively straightforward solutions. In contrast, policy, cultural, economic, political, and professional issues may be of equal consequence yet more difficult to resolve. Science, technology, and technology policy thus are of great importance but cannot be considered apart from the ways in which people will use telemedicine.

TECHNOLOGY AND POLICY OBJECTIVES

The objectives over the next 15 years are the following:

1. DEVELOP A TELECOMMUNICATIONS INFRASTRUCTURE THAT IS COMPREHENSIVE, RELIABLE, UBIQUITOUS, AND COMPATIBLE ACROSS APPLICATIONS

Such an infrastructure should provide affordable bandwidth that is sufficient to serve users' specific needs. Its development will be dependent upon the continued deregulation of the telecommunications industry and will involve the leveraged use of many technologies that have been spawned by and for other industries.

2. PROVIDE TECHNOLOGICAL INTERFACES THAT FACILITATE EFFECTIVE USE OF THE INFRASTRUCTURE AND ITS COMPONENT SYSTEMS

These interfaces may involve systems capable of rendering information from multiple sensory modalities, in conjunction with a variety of artificial intelligence applications as aids to decision making. They will require modularity, open architecture, and compliance with fundamental interface protocols. In the near term, emphasis should be placed on store-and-forward systems that require limited bandwidth and on means of providing home health care electronically.

3. SHAPE THE LEGAL AND REGULATORY INFRASTRUCTURE IN WAYS THAT WILL FACILITATE MEDICAL COMMUNICATION

At the professional level, such issues as interstate licensure and credentialing of physicians must be addressed. The telecommunications and information industries must develop rational and affordable tariff structures. Legislation must be passed to ensure the security of personal health information.

4. DEVELOP RATIONAL, TECHNOLOGICALLY NEUTRAL POLICIES FOR PUBLIC AND PRIVATE PAYERS

Coverage and payment policies should be established that cover the entire range of telemedicine applications and technologies. Means should be developed for assessing the appropriateness of health services provided via telemedicine. Outcome-based quality improvement programs will be of great importance in assuring quality, cost-effective medical care.

5. PROVIDE APPROPRIATE CONTENT TO CONSUMERS, PATIENTS, AND PROVIDERS THAT WILL ENHANCE HEALTH CARE OUTCOMES

The process for conveying information should permit the user to follow the links between data, inferences, and conclusions. Authentication, access control, confidentiality, integrity, and attribution are key requirements for health-related advice and decision making, and telemedicine systems must be designed to adhere to a high standard of auditability; an “anonymous” Internet will not suffice. It should be possible automatically to capture data on outcomes that result from decisions made on the basis of information provided by the system. The system should support an approach to outcomes research that will improve the quality of care.

TECHNOLOGY AND POLICY ROADMAPS

The requirements and drivers that are necessary to meet the objectives for advanced telemedicine in the near (0 to 3 years), intermediate (3 to 6 years), and far (6 to 15 years) terms are itemized in the following set of tables.

OBJECTIVE 1: DEVELOP A TELECOMMUNICATIONS INFRASTRUCTURE THAT IS COMPREHENSIVE, RELIABLE, UBIQUITOUS, AND COMPATIBLE ACROSS APPLICATIONS

The development of a telecommunications infrastructure ensures that a national telecommunications network capable of supporting the development of advanced telemedicine is in place, that it is affordable even for relatively remote areas with a low volume of telemedicine services, and that it is reliable in its operation. Such a network should be capable of providing adequate bandwidth to perform complex information transfers at a high bit rate throughout its range.

A national telecommunications network must be readily available and affordable

OBJECTIVE 1: Develop a telecommunications infrastructure that is comprehensive, reliable, ubiquitous, and compatible across applications

Technical and/or policy attribute that drives success for this objective	Units of Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Continued deregulation of telecommunications industry	Infrastructure cost Competition between telecom providers	Decreasing costs Increasing competition	Lower telecom costs due to increased competition	Fully competitive telecom industry	
Affordable bandwidth for specific user needs	Bits per second	28KB	28KB to 1.5MB Store-forward systems for sites with low bandwidth	1.5MB to 45MB Higher bit rate requirements for entertainment industry expand infrastructure Store-forward still available	>45MB Store-forward not needed because of availability of adequate bandwidth, but available where convenient
Infrastructure deployment	% of infrastructure penetration into underserved areas	Many rural areas currently underserved	10%	35%	90%

Telemedicine must be easy to use

New technology is required to
integrate a wide range
of information

OBJECTIVE 2: PROVIDE TECHNOLOGICAL INTERFACES THAT FACILITATE
EFFECTIVE USE OF THE INFRASTRUCTURE AND ITS COMPONENT
SYSTEMS

The development of technological interfaces is of fundamental importance to ensure that telemedicine is easy to use (essentially foolproof) by both patients and providers, regardless of the simplicity or complexity of an application. It addresses the need for common interface standards and the adoption of advanced technologies (e.g., intelligent systems, sophisticated remote sensing) for health care purposes.

For physical examination, new technology required includes devices for the acquisition of a wide range of kinds of information, varying by sensory modality (e.g., auditory, visual, and haptic sensation). Infrared and ultrasonic instruments may permit the collection of images and physiologic data by noninvasive means, reducing the need for trained personnel on site with the patient. Display technology may involve such technologies as virtual reality, often integrating force-feedback for performance of remote interventions.

Finally, the process of making decisions may be facilitated by the integration into these systems of pattern recognition and artificial intelligence technologies such as genetic algorithms, simulated neural networks, case-based reasoning, expert systems, and other approaches to optimization.

OBJECTIVE 2: Provide technological interfaces that facilitate effective use of the infrastructure and its components systems

Technical and/or policy attribute that drives success for this objective	Units of Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Modularity, open architecture, & compliance with fundamental interface protocols	• Data reporting standards	• Diverse formats, frequently incompatible	• Standards defined by industry & adopted by 30%	• Standards adopted by 75%	• Standards adopted by 90%
Multimedia communications engine	• Copy per unit	• Prototype models • Custom systems	• First hardware cycle (~\$1,000) • PC-level functionality	• Commercial prototypes (~\$500) operable across WWW	• Fully commercial and widely available
Ability to convey requisite sensory data, transmit force, virtual reality (VR)	• Sensory modalities • Equipment for robotic manipulation	• Visual, auditory, cognitive (text), prototype robotic movement, & prototype V.R.	• Haptic sensation • Continued development for robotics for motion, V.R.	• First hardware for haptic sense • Commercially available V.R. interface • Commercial prototypes for robotic manipulation	• Integrated multi-sensory transmission • Commercially available robotic manipulation Fast, realistic V.R. interface
Telemedicine systems architecture that supports authentication, access control, confidentiality, integrity & attribution via public networks	• % telemedicine systems with verifiable security and auditable content	• Prototype model architectures	• First deployment & evaluation of accountable models over public networks	• Accountable models adopted by 100% of telemedicine systems	• Accountable models adopted by 100% of telemedicine systems
Development of more sophisticated, less expensive telemedicine technology for home health care	• Cost to provide unit of service • Cost to provide care for an episode of illness	• Prototype PC-based systems available	• Use existing TV cable system, current PC & video camera • Use available SW interface	• Fiber TV cable with T1 capability & some wireless access • Enhanced SW with advanced menu system • Lower cost PC sensor system	• Fiber TV cable with T3 capability & wireless access • Touch-screen menu system >15 low-cost sensors • Data from advanced sensors
Low cost monitoring technologies	• Condition-specific devices	• Limited PC-based sensors	• Upgraded sensor/transmitters: - BP - Temp - Pulse - Oximetry - EKG • Lower cost PC & camera	• Additional sensors Integrated system cost: <\$2,000 • Basic personal status monitor	• >15 sensors • Non-invasive glucose sensor • Integrated system cost: <\$1,000 • Advanced personal status monitor
Advanced technologies developed primarily for military applications, adapted to other sectors	• Dual-use, cost-effective technologies	• Consultation • Visible human, teleradiology & telepathology • Neural nets, automatic target recognition (ATR) algorithms	• Decision support • Advanced applications of Visible Human database • Primitive VR training for surgeons	• Multimedia interaction & projection • Extended Visible Human applications	• Telerobotic assisted surgery • Advanced VR for tactile surgical training using Visible Human database
Telemedicine systems integrated with intelligent agents and artificial intelligence (AI) for decision support		• Some pattern-recognizing & diagnostic neural nets • Expert algorithms for diagnosis & triage	• Development of image analysis software for medical imaging • Computerized algorithms for triage & patient management • Tumor classification & detection	• Commercially available intelligent systems: ~5%	• Commercially available intelligence systems: ~50%

OBJECTIVE 3: SHAPE THE LEGAL AND REGULATORY INFRASTRUCTURE IN WAYS THAT WILL FACILITATE MEDICAL COMMUNICATION

Current regulations impede the development of telemedicine

This objective addresses problems posed by the current legal and regulatory infrastructure. These problems include professional licensure, which currently is done on a state-by-state basis, with each state reserving for itself the right to determine who may practice health services on patients within its boundaries. Some states recently have considered or adopted legislation that would increase the barriers to the interstate practice of telemedicine. Legislation and case law pertaining to the privacy and security of personal health legislation will need to be revised to meet the demands of electronic data transfer, and standards for who may have access to this information must be tightened. Continued deregulation of the telecommunications industry should lead to changes in rate structures that make transmission of health data more affordable even for relatively remote geographic areas.

OBJECTIVE 3: Shape the legal and regulatory infrastructure in ways that will facilitate medical communication

Technical and/or policy attribute that drives success for this objective	Units of Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Establish national licensure for health care professionals	Passage of legislation	50 different state licensing systems, with practice limited to licensees within each state	Legislation enacted allowing physicians to practice electronically across state lines	Legislation enacted for other providers to practice electronically across state lines	National licensure for all health care providers to practice electronically
Legislature to insure the security and surety of personal health information	Establishment of encryption standards Establishment of access rights	No agreed standards across entire health care industry or telecom infrastructure	Purchasers, consumers, & legislators agree on requirements for encryption and access	Testbeds demonstrate security and data reliability	All electronically transmitted personal data adequately encrypted, access restricted appropriately
Development of rational & affordable tariff structures by industry	% of telecom companies providing altered rate structure	Arbitrary rates, variability between and within regions	20%	50%	95%

OBJECTIVE 4: DEVELOP RATIONAL, TECHNOLOGICALLY NEUTRAL POLICIES FOR PUBLIC AND PRIVATE PAYERS

This objective deals with the establishment of national policies for telemedicine that should be developed for both private and public payers. At present, Medicare policy is to deny coverage for telemedicine services, while some states have adopted their own approaches to coverage and payment for Medicaid. There is no agreement on policy in the indemnity insurance industry, which has not yet approached the issue directly. Idiosyncrasies of the present system (e.g., denial of payment for telephone consultation) may eliminate an entire class of cost-effective services for remote areas with little money to fund more expensive interactive TV telemedicine.

Policy for telemedicine should cover all technologies and be cost-effective for all participants

A coverage policy that is technologically neutral (that is, that covers cost-effective and medically effective applications regardless of the technological specifications) is needed.

OBJECTIVE 4: Develop rational coverage, payment, utilization, and quality improvement policies for public and private payers

Technical and/or policy attribute that drives success for this objective	Units of Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Nationally consistent telemedicine coverage and payment policy	Telemedicine services covered by payers	Teleradiology, telepathology, & a few other applications	Completion of outcomes study on telemedicine for consultation	HCFA approval of coverage for interactive video consultations, home health, store & forward	Coverage of most telemedicine services, including remote interventions
		Medicaid & private insurers in some regions	Continued evaluation	Continued outcome studies	Extensive competitive contracting and capitated telemedicine
		Coverage not an issue for DoD, VA, Indian Health System	Expansion of telemedicine to correctional institutions	Non-fee-for-service market grows substantially	
Nationally consistent telemedicine quality improvement policy	Outcome-based QI (OBQI) systems in place	None currently, but OBQI not available for some services (e.g., home health care)	Pilot OBQI programs	Preliminary OBQI standards for interactive telemedicine established	OBQI standards for most telemedicine applications established
			Development of model for approach to OBQI	Expansion of research on OBQI 35% available	OBQI research on most telemedicine applications 90% available
Nationally consistent telemedicine utilization policy	Appropriateness & need for telemedicine established in specific conditions	None currently, those in operation often restrict access inappropriately	Preliminary research data on frequency & intensity of use	Initial standards set a reasonable range for utilization	Well-established standards define both under- and over-utilization

OBOI schemes should be developed

Outcome-based quality improvement (OBOI) schemes should be developed. These could ensure quality care in a way that is not now possible with methods based solely on documentation of processes (as is the case with HEDIS at present). Finally, both underutilization and overutilization of health services may have an adverse effect on patient outcomes. As telemedicine becomes more widespread, it will be possible, and important, to establish standards for appropriate telemedicine care.

Standards for telemedicine will be necessary

Considerable research will be required to meet this objective and will consist of national, multisite health services research.

OBJECTIVE 5: PROVIDE APPROPRIATE CONTENT TO CONSUMERS, PATIENTS, AND PROVIDERS THAT WILL ENHANCE HEALTH CARE OUTCOMES

Access to and integrity of user information is essential

The provision of accurate and appropriate content to users is a complex problem to which a multi-faceted solution is essential. For patients, providers, and payers, both access to and integrity of information must be ensured.

This process involves several steps, including the:

- Determination of which data are appropriate and necessary for which users
- Specification of the data to be available, acquisition and processing of those data
- Evaluation of the data (e.g., assuring their integrity)
- Updating and revision of data and information over time
- Appropriate and efficient use of the data
- Evaluation of outcomes ensuing from their use

Evaluation of outcomes can be used to improve the system

This evaluation could then be used to modify the information system itself. Considerable research and development must take place to support this objective, but its attainment will itself facilitate future research through automation of data collection respecting both outcomes and processes of health care.

OBJECTIVE 5: Provide appropriate content to patients, providers, and payers that will enhance health care outcomes

Technical and/or policy attribute that drives success for this objective	Units of Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Development of standards for data content and format in electronic health care transactions	Common standards Clinical & financial data requirements	Diverse standards Lack of collaboration among health care providers and purchasers	Universal agreement on: • Data needs • Formats	<i>de facto</i> standards emerge All government health care purchasing entities agree on set of standards	Universal adoption of common standards 90% availability nationally
Integrated system for capture, analysis & reporting of critical epidemiologic information internationally	% availability nationally	Somewhat less than systematic analysis & reporting	Prototype software and protocol development	20% availability nationally	50% available internationally
Integrated systems for capture & analysis of outcome data	% of treatment facilities with system	APACHE III database for critical care outcomes Individual systems for selected conditions	Development of standards for variable inclusion Commercial database development for global outcomes	Database development for condition-specific outcomes 5% availability	Integration of medical & utilization outcome data 80% availability
Assessment of health service needs of local population, including both consumers and providers	% of completed needs assessment	Seldom conducted, no systematic approach	<10%	<35%	80%
Integration of scientific literature access into telemedicine systems	% of telemedicine systems with access	Separate systems for telemedicine services and literature search	<10%	<35%	90%
Availability of health information to consumers	% of population	Available from libraries, book stores, some providers	<10% of population	35% of population	90% of population

The problem is not trivial. Cognitive scientists have demonstrated that the availability of greater amounts of information frequently degrades decision making, and providers often will not use information if it is inconvenient to them to do so. Means must be developed for preprocessing information that facilitates the process of making good decisions. Patients, on the other hand, frequently have too little information available for the appropriate management of their own health. There is a great demand for such information. Finally, attainment of this objective is predicated on the fact that end users' needs must be assessed carefully, in each health care environment, in order to provide a system that will be used.

There is a great demand for easily accessible and available health and health care information

TECHNOLOGY AND POLICY DRIVERS

A summarized list of the principal technologies and policies that will drive the success of the above objectives follows.

- **CONTINUED DEVELOPMENT OF AN AFFORDABLE, UBIQUITOUS, HIGH CAPACITY, NATIONAL TELECOMMUNICATIONS NETWORK**

Without such a network, telemedicine will not be available in those areas of greatest need for services. At present, gaps in the availability of adequate transmission media and the cost of telecommunications access for remote areas often make the use of telemedicine impractical.

- **REGULATORY AND POLICY CHANGES THAT ELIMINATE FACTORS CURRENTLY RESTRICTING THE PRACTICE AND SPREAD OF TELEMEDICINE**

Without promulgation of a national coverage and payment policy, few providers will be interested in telemedicine. Without change in the current state legislation regarding licensure, unrestricted interstate practice of telemedicine is impossible.

- **CONDUCT OF RESEARCH ON THE EFFICACY, EFFECTIVENESS, AND COST-EFFECTIVENESS OF SERVICES PROVIDED BY TELEMEDICINE IS ESSENTIAL**

This research will facilitate development and refinement of policy and will permit the development of practical, effective solutions to specific health care problems.

CRITICAL INFRASTRUCTURE AND CORE COMPETENCIES

The following table summarizes the list of key technology and policy drivers and the infrastructure and core competency areas to which they pertain.

KEY DRIVERS	INFRASTRUCTURE AND CORE COMPETENCIES
National communications network	<ul style="list-style-type: none">• High bandwidth capacity• Affordable tariff structure• Available throughout the country
Regulatory and policy change	<ul style="list-style-type: none">• Development of public & private coverage policy• Development of outcome-based quality assurance policy• Model legislation for state licensure (short-term)• National telemedicine licensure (long-term)
Research on efficacy, effectiveness, cost-effectiveness	<ul style="list-style-type: none">• Efficacy studies with new and existing technologies• Medical effectiveness of the complete range of telemedicine applications across programs• Cost-effectiveness of specific applications of telemedicine (e.g., home health, video consultation, monitoring) for both the individual unit of service and the entire episode of illness
Health provider education	<ul style="list-style-type: none">• Use of telecommunications technologies for medical education• Use of telecommunications technologies for Continuing Medical Education• Introduction of medical students and residents to use of telemedicine in clinics, in both rural & urban settings• Emphasis in training on use of information technologies

The use of telecommunications technology to provide medical care may lead to a radical restructuring of the way health services are provided in this country. Although the effect of telemedicine on overall costs is difficult to predict, certain specific applications show potential for being very cost-effective. Even when costs increase, this may reflect greater access to care that may not be available through conventional means. Access in remote or impoverished areas will not improve, however, without the development of a nationwide network that will support the telemedicine applications that are necessary in a specific geographic region.

A nationwide health information network can radically change health services

A wide range of policy and regulatory changes are required

Even when such a network is available, unless significant policy and regulatory changes occur in the near future, the spread and growth of telemedicine will be significantly impeded. Absent a coverage and payment policy, providers are unlikely to be interested in greater amounts of work with no (or very limited) compensation. They will be unable to engage in telemedicine outside the boundaries of their own states without significant reform of provider licensing statutes. Licensure currently is regulated by the individual states, and most seem responsive to the self-protective inclinations of their own providers who often wish to limit outside competition.

Informed policy and effective technology research is needed

Research is necessary to facilitate the development of an informed policy and to permit the use of effective, practical telemedicine solutions that improve patient health outcomes. The current social, political, and economic climate demands that health services be provided in a cost-effective manner, without compromising the health or the rights of individual patients.

Exposure to telemedicine in the medical curriculum is needed

Finally, the retarded spread of telemedicine is in part a function of resistance on the part of providers, especially physicians. Many are unfamiliar with and even suspicious of telemedicine technology, and well-established practice patterns may be difficult to change. Some providers see telemedicine as a threat to existing referral networks and even to the viability of their own practices. Exposure of health care professionals to telemedicine from the start of their educational careers will serve to reduce this impediment to telemedicine expansion.

OPPORTUNITIES AND SHOWSTOPPERS

OPPORTUNITIES

THE STATE OF HEALTH CARE DELIVERY IN THE NATION IS CHANGING

The state of US health care is changing rapidly due to the convergence of several dynamic developments, including the:

- Economic incentives for containing US health care costs
- Recent trends in health care delivery away from hospitals toward ambulatory, home or community-based care
- Demographic increase in the US population of the elderly
- Increased interest and responsibility of individuals to take better care of themselves, their families, and make more decisions about medical care
- Health information is the most requested information service from media sources

In particular, the forces for health care cost containment coupled with the rapid development of information networks pose new opportunities for delivering health care services outside of the traditional hospital setting to remote sites, including the home.

**CONVERGENCE OF TECHNOLOGIES FACILITATES THE DEVELOPMENT OF
TELEMEDICINE**

Telemedicine reflects the convergence of technological advances in a number of fields, including telecommunications, space science (e.g., satellites), materials science, computer and software engineering, artificial intelligence, perceptual psychology, robotics, and medicine. Cross-fertilization can be expected to lead to a rapid pace of new developments.

SPENDING FOR HOME HEALTH CARE DELIVERY IS GROWING

In 1996, for example, the total for all home health care delivery spending is expected to total more than \$27 billion, based on concurrent estimates from FIND/SVP, a New York City market research firm, and the Congressional Budget Office (CBO).

Further, the National Association of Home Care (NAHC) estimates indicate average 12% annual increases in overall home health visits.

SHOWSTOPPERS

THE DEVELOPMENT OF NEEDS-BASED TELEMEDICINE APPLICATIONS WILL REQUIRE SUBSTANTIAL PRELIMINARY WORK

Although one would anticipate that a reasonable business plan would involve thorough investigation of market needs and opportunities, few telemedicine programs have undertaken this kind of research prior to their establishment. Consequently, many have floundered. This investigative work is not overly burdensome but requires careful thought and planning. The likely outcome is the development of viable telemedicine programs that provide a durable base for expansion of services over time.

AN EXISTING POLICY OF DENYING COVERAGE FOR SERVICES PROVIDED BY TELEMEDICINE IS PROBLEMATIC

Although it frequently is stated that there is no telemedicine policy in this country, in fact, for Medicare at least, there is a policy of denying telemedicine coverage. Without modification of the “face-to-face” rule and formulation of a payment scheme, fee-for-service telemedicine can be expected to languish. This situation poses no barrier, however, for those who wish to explore contract or fully capitated coverage schemes (e.g., managed care organizations, prison telemedicine).

THE TECHNOLOGY AND ITS EXPLOITATION ARE IMMATURE

Because telemedicine programs are relatively new, treat small volumes of patients, are generally not self-sustaining, and engage the services of relatively few providers, it is not yet possible to establish standards for practice without running the risk prematurely of locking telemedicine into inefficient standards of practice (e.g., a physician at each end of an interactive video conference), or into less than optimal software or hardware configurations.

MANAGING THE AVAILABILITY OF INFORMATION MAY BE A DELICATE BALANCING ACT

Too little information makes it impossible adequately to manage a patient's condition or for consumers to look after their own health. Too much information is problematic for other reasons. The complexity of managing large databases is a nontrivial problem, as is the necessity to ensure the integrity and regular updating of such databases. Many providers already feel overloaded with information, but part of the problem is that it is given to them without any preprocessing. It thus becomes necessary continually to separate the wheat

from the chaff. More information is not always better. What providers need is more useful information. For consumers, the problem is one of making reliable health information more accessible so they can assume more responsibility for their own health.

RESEARCH IS FRAGMENTED, AND THE CONDUCT OF RESEARCH IS DIFFICULT AT PRESENT

There have been few good evaluations of the effectiveness and economic practicality of telemedicine. The evaluation component of most extant government-funded demonstration projects is weak and, in any event, can only provide a snapshot of what is happening in any given program. Significant opportunities for research exist, but careful scientific study is expensive, and it is unclear who will support this work at adequate levels. Definitive investigation of certain questions will be impossible until the technology has disseminated more extensively, practice patterns have stabilized, and patient volumes have increased. A comprehensive program of careful research is essential.

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1 glossary

APACHE III: Acute Physiologic and Chronic Health Evaluation. Scoring system and database containing extensive data on critical care inpatients. Includes outcomes, demographics, medical history, clinical/physiological variables, and treatment variables.

Bandwidth: As commonly used among telemedicine practitioners, this refers to the amount of information that may be transmitted across a telecommunications medium in a fixed amount of time; usually expressed as number of bits (binary digits) per second.

Expert systems: Software algorithms devised for classification, prediction, and decision-making. Based on the logical approach of experts in a given content area to solving specific problems in that area, expert systems essentially mimic the reasoning of experts.

“Face-to-face” rule: A policy established by the Health Care Financing Administration (HCFA), the federal agency that administers Medicare and Medicaid. This policy states that when medical care is ordinarily given a patient by a provider in person (e.g., physical examination), Medicare will pay for that service only when it is provided in person. That is, telephone consultation is not covered by Medicare in such cases, and by extension, neither is most telemedicine.

Genetic algorithm: A technique for optimizing statistical modeling and control processes derived from research on artificial life. Existing solutions undergo simulated genetic processes of mutation and crossover, and the “offspring” are tested to determine whether they provide an improved solution. The most “fit” of the offspring are retained and used to produce new generations of solutions.

Haptic sensation: Sense of touch; tactile sensation.

Health Employer Data & Information Set (HEDIS): A set of performance standards devised for the evaluation of managed care organizations (MCOs) by the National Committee on Quality Assurance (NCQA), a credentialing organization for MCOs.

Outcome-based quality improvement (OBQI): Collection of data on different aspects of patient health status over time in order to assess how health outcomes are affected by different health services. Outcomes, usually adjusted statistically for patients’ severity of illness, are used to modify health care practices.

Personal status monitor: Telemetry device designed to be worn or carried by an individual, permitting remote monitoring of a range of physiologic parameters (e.g., pulse, blood pressure, oxygen saturation).

Simulated neural networks: Any of a variety of adaptations of artificial intelligence that simulate the relationships between neurons in the brain and their interactions with one another in response to experience. A neural network can be trained to recognize patterns in data by presenting a data set repeatedly and providing the network with feedback about the accuracy of its predictions or classifications. Using the feedback, the network adjusts its functioning to minimize the error in the model.

Store-and-forward: An approach to telemedicine that is designed to operate outside real time. That is, information may be placed into the system and transmitted for review by a remote consultant, most frequently for analysis at a later time.

1 glossary

T1: Digital telecommunications lines with a capacity of 1.544 megabits per second (mbps).

T3: Digital telecommunications lines with a capacity 28 times that of T1, or 44.736 mbps.

Telecommunications infrastructure: Equipment, switches, and transmission media (copper wire, fiber-optics, satellite, microwave, radio) that comprise the communications network linking end-users’ equipment.

Telemedicine: The use of telecommunications and information technology to provide health services to persons who are at a distance from the provider.

Telemedicine interface: Hardware and software by means of which different kinds of information are placed into and displayed on a telemedicine system by users.

Virtual reality: Graphical simulation of three-dimensional reality. Used in telemedicine for display of complex anatomical images and to facilitate the remote manipulation of instruments used in various medical interventions.

Visible Human database: High resolution digital anatomic images of two dissected adult human cadavers, used for teaching general anatomy.

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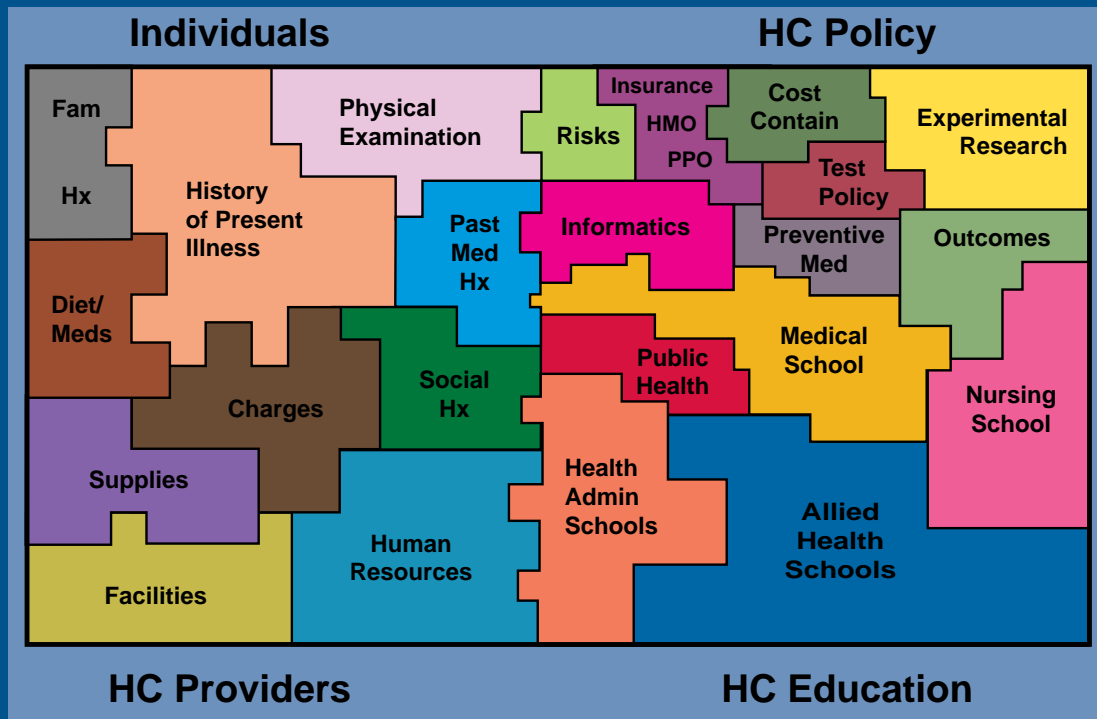
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HEALTH AND HEALTH CARE INFORMATICS TECHNOLOGY ROADMAP

The deployment of seamless, universal, comprehensive and integrated Health and Health Care Informatics (HHI) will determine the future quality of health and the quality and availability of health care in the nation. The following technology and policy Roadmap addresses the critical aspects of the successful development and deployment of HHI-based systems of the near, intermediate and long term future.



DESCRIPTION

HHI can improve health, the quality of health care and reduce total health care cost

A new Health and Health Care Informatics*¹ (HHI) paradigm offers the greatest potential for improving the nation's health* and quality of health care* while reducing total health care costs.* This potential is based on the opportunity to disseminate health and health care information in a timely fashion, at the point of need, to monitor its use, and to assess health care practices. This should lead to dramatic improvements in health care cost-efficiencies* and to the determination of cost-effectiveness* in health care cost-containment* situations.

The need for this new paradigm is now acute. Health care is undergoing considerable upheaval due to decades of unchecked costs increase and to maldistribution. New enterprise forms are emerging with different health care delivery and financing models and are leading to the formation of new alliances and partnerships, competition at an individual component service level, and blurring of traditional institutional boundaries. Consumers, meanwhile, are increasingly educated and are becoming more proactive in improving their own health and in determining their own health care needs.

The new HHI paradigm expands data management to all types of data and to all aspects of health care

Current health care information systems are predominately institution-based, or more narrowly focused on specific management needs or on only data* acquisition, display and storage tasks. The new HHI paradigm expands data management to all types of data and to all aspects of health care (see Table A)² and includes comprehensive information* generation through the use of knowledge.* The seamless integration and universal (yet secure) access of these expansions generate the new informatics paradigm.

Future systems adopting the new HHI paradigm must be capable of handling all measures of complexity characteristic of health and health care (see Table A) while maintaining flexibility, responsiveness and quality. These systems must deal with all interactions of health care regardless of where, when or how the interactions take place (e.g., face to face, through robotics* or by telehealth).³

This Roadmap describes the development of HHI

This HHI Technology Roadmap addresses the development of new HHI to provide seamless, universal, effective and integrated health and health care information and services.

* The glossary defines basic and key terms in health and health care. Words with critical conceptual definitions in the glossary are marked with an asterisk (*).

TECHNOLOGY AND POLICY OBJECTIVES

The objectives over the next 15 years are to:

- 1. DEVELOP HEALTH AND HEALTH CARE INFORMATION SYSTEMS ENABLING UNIVERSAL ACCESS, COLLABORATIVE HEALTH CARE DELIVERY, AND IMPROVED HEALTH CARE VALUE (QUALITY/COST)
- 2. DEVELOP HEALTH AND HEALTH CARE INFORMATION SYSTEMS ENABLING APPROPRIATE AND EFFICIENT ON-LINE ACCESS, DISTRIBUTION, AND PROCESSING OF RESOURCES REQUIRED BY HEALTH CARE PROVIDERS, CONSUMERS AND THE EXTENDED US HEALTH CARE SYSTEM STAKEHOLDERS
- 3. ESTABLISH HEALTH AND HEALTH CARE LEGISLATION, REGULATION AND POLICIES THAT ENSURE THE SECURITY, CONFIDENTIALITY AND SURETY OF PERSONAL HEALTH INFORMATION WHILE ALSO PROVIDING THE HEALTH CARE COMMUNITY USE OF THE HHI IN ORDER TO DELIVER HIGH QUALITY, COST-EFFECTIVE CARE TO PATIENTS. IN ADDITION, ALLOW ACCESS TO IDENTIFIER DELETED INFORMATION TO PROMOTE EFFECTIVE HEALTH CARE MANAGEMENT, POLICY AND EDUCATIONAL PROGRAMS
- 4. ESTABLISH A SYSTEMS FRAMEWORK TO IMPROVE THE TESTING AND REGULATION OF HHI SYSTEMS AND COMPONENTS

TECHNOLOGY AND POLICY ROADMAPS

A list of the requirements necessary to meet the objectives in the near (0 to 3 years), intermediate (3 to 6 years) and long (6 to 15 years) term future is represented defined by the Roadmaps that follow.

**OBJECTIVE 1: DEVELOP HEALTH AND HEALTH CARE INFORMATION SYSTEMS
ENABLING UNIVERSAL ACCESS, COLLABORATIVE HEALTH CARE
DELIVERY, AND IMPROVED HEALTH CARE VALUE (QUALITY AND
COST)**

INFORMATION ACCESS & IMPROVED HEALTH

A health information system must maintain confidentiality of records

Balancing the requirement for confidentiality of the health record is the need to use HHI-based systems to address the numerous health care applications including healthcare delivery, payment, research, education, etc. Nonhealth record data must also be captured and maintained for a wide range of health and health care measures including patient status, outcomes, cost-efficiency and cost-effectiveness, quality, consumer productivity and health provider performance. As personal health and health care records become electronic, great care must be taken to protect the individual's privacy, dignity and autonomy. HHI-based systems should protect the interests of the consumer/patient.

OBJECTIVE 1: Develop health and health care information systems enabling universal access, collaborative health care delivery, and improved health care value (quality and cost)

Technical and/or policy attribute that drives success for this objective	Units of Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Care delivery effectiveness measures	Shared decision making	Minimal, some interactive video	Limited, some interactive video & mediated online resources	Expanded interactive video & mediated online sources	Pervasive interactive video & collaborative online sources
	Consumer access & satisfaction	Unequal & mixed	Unequal & mixed	Greater options & increased satisfaction	Numerous & flexible options; proactive & satisfaction
	Care service quality & costs	Anecdotal quality/costs improvements	Increased cited quality/costs improvements	Scaled, validated quality/costs improvements	National, validated quality/costs improvements
	Consumer productivity	Unnecessary use of care facility services, great amount of sick leave	Greater consumer interaction with health information options	Expanded consumer interaction with health information options	Collaborative health education & care services; unnecessary services eliminated; reduced sick leave
Care-providing roles	Care foci	Treatment oriented	Some health education & prevention emphasis	Increased education, improved prevention and treatment	Prevention oriented; individual, family & care provider collaboration; upgraded remote treatment

**OBJECTIVE 2: DEVELOP HEALTH AND HEALTH CARE INFORMATION SYSTEMS
ENABLING APPROPRIATE AND EFFICIENT ON-LINE ACCESS,
DISTRIBUTION, AND PROCESSING OF RESOURCES REQUIRED BY
HEALTH CARE PROVIDERS, CONSUMERS AND THE EXTENDED US
HEALTH CARE SYSTEM STAKEHOLDERS**

*A network of subsystems must
be developed to help address
all requirements*

It is apparent that no single, de novo system can address all requirements of the broader health and health care information environment (see Table A). Instead, subsystems that deal with some requirements and are able to interact with all other subsystems must be developed. Eventually, these subsystems together can address all requirements of the broader health and health care system.

*Future systems must be developed as decentralized, heterogeneous networks of
subsystems linking consumers and providers of health and health care information and
services. Software objects* will be developed to serve as the basis of all subsystems
and applications.*

*The network will serve consumers
and health care professionals at
any time, anywhere and from
any platform*

These systems will enable consumers to access health information and health care services at any time, anywhere and from any media platform.³ Likewise, these same systems will service the health care professionals' requirements for:

- Caring for the individual, e.g., a patient's health record, list of medications
- Provider support for managing an office or offices to managing medical centers
- Health care policy formulation and distribution, e.g., outcomes research, practice guidelines
- Health care education e.g., medical schools, nursing schools, allied health schools, etc.

*"Broad access to health information
services helps meet cost
management goals by
reducing demand."*

Such systems not only have the potential to revolutionize health information access and corresponding healthcare, but there is also a growing body of evidence that such services can better address costs management goals. The Health Project Consortium, a public and private sector team of health policy experts, business leaders, health insurers and government officials, agreed that "broad access to health information services helps meet cost management goals by reducing demand."⁴ The premise of the Consortium is that consumer access to health information services would *"reduce the burden of illness and thus the need and demand for medical services."*⁵ Additional managed care organizations' and employers' programs' evidence supports this claim.⁴

**OBJECTIVE 2: Develop health and health care information systems enabling appropriate and efficient on-line access,
distribution, and processing of resources required by health care providers, consumers, and the extended
US health care system stakeholders**

Technical and/or policy attribute that drives success for this objective	Units of Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Health object classes development & utilization	Encapsulation of legacy systems # of health care-usable components commercially available	1% Index of 100	5% 100K	30% 1M	>90% 100M
Health object classes management & validation	Health care classes libraries Validation pilots	Limited commercial, limited proprietary health libraries N/A	Upgraded commercial & some cooperatives health libraries Limited across locations & specialties	Additional commercial & cooperatives health libraries Additional across locations & specialties	Extended commercial & cooperatives health libraries Extended across locations & specialties
Health platforms & user interfaces	Technology platforms	Computer (in-facility, some mobile)	Computer, kiosks, some interactive TV, telephone, mobile devices (e.g., PDAs)	Computer/interactive TV, kiosks, telephone, advanced mobile devices (e.g., PDAs, beepers, watches, etc.)	Any platform, Any time, Any where
Systems technologies maturation & integration	Technology capability level (decision support systems, multimedia databases, security hardware/software, etc.)	Primitive collaborative computing tools	Upgraded collaborative computing tools	Improved collaborative computing tools	Advanced collaborative computing tools
Multimedia health & health care information	Information levels	Data Image, audio, slow video	Data, information Improved image, audio & video Initial "Edutainment"	Data, information, some knowledge Extended image, audio & video Extended "Edutainment"	Data, information, knowledge Advanced image, audio & video Advanced "Edutainment"
Health information systems developments	Development participants	Some public and private sponsored programs	Increased public and private sponsored programs	Increased public and private sponsored programs	Sponsorship primarily commercial
Systems effectiveness measures	System flexibility & reliability	Some proprietary, some open; significant downtime	Additional open, some downtime	Common open, some downtime	Flexible & robust

*A componentware methodology
should be adopted for future
HHI systems*

COMPONENTWARE⁶

Component manufacturing and assembly have led to significant cost reductions in many industries, especially the computer hardware industry. Software componentware, based on object technology⁷ and used to assemble subsystems and applications, is the only credible, cost-effective and scaleable methodology available for HHI to build systems in the near, intermediate and long terms.

In the traditional software model, each application must support a set of defined users. This relationship has often led to the development of proprietary interfaces and application designs. As a result, such applications have been characteristically difficult to develop and to maintain. These systems were not designed to meet the complexity, flexibility, responsiveness and quality requirements of needed future systems.

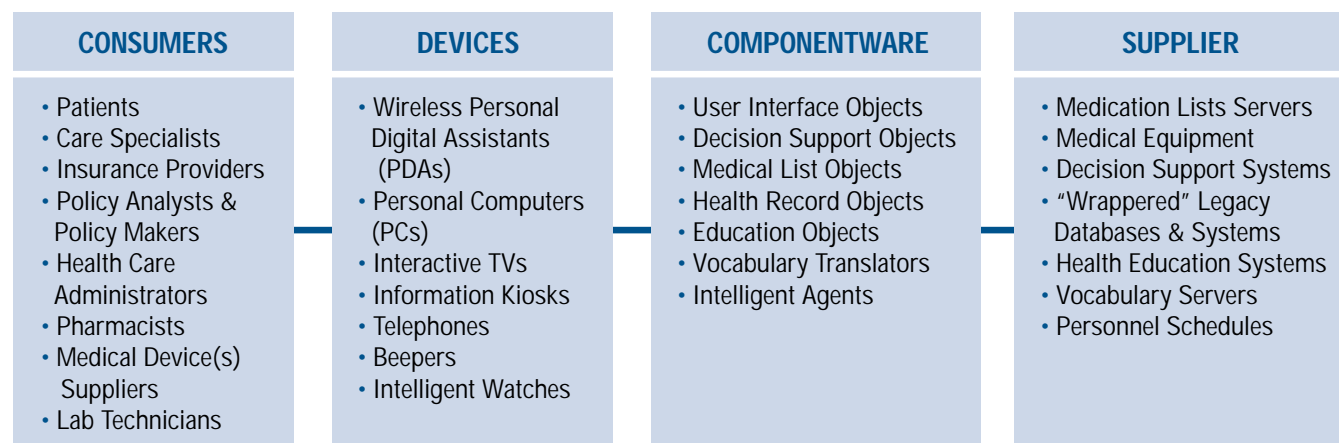
*Legacy systems must function as
part of future HHI systems*

Current health information systems are often proprietary applications in specific areas and, as a result, difficult to integrate. The current model has limited the evolution of information systems to meet demands. Nevertheless, these “legacy” systems must remain and play important roles during the transition to the future componentware systems envisioned for the HHI. “Object wrappers” (i.e., encapsulation) around these legacy systems will allow legacy systems to interact as objects and function as part of future HHI systems.

*Componentware will link HHI
consumers with suppliers*

Componentware developments will link consumer applications with the health and health care information supplier (see Figure 1). In addition, the standards associated with and established by

FIGURE 1: Componentware developments will foster a plug-and-play development arena for future open-architecture, object-based health and health care information applications



these componentware developments will foster the development of a “plug-and-play” arena for future open-architecture, object-based health and health care applications.

Componentware to be developed include functionality such as the following:

- User Interface
- Decision Support
- Medication List
- Health Record
- Education
- Cost & Outcome Analysis
- Vocabulary Translation
- Intelligent Agents

Users may include anyone requiring information system access, including:

- The General Public
- Patients
- Health Care Workers
- Third Party Payers
- Health Care Policy Analysts & Makers
- Healthcare Administrators
- Researchers

Any device may be used to access health information:

- Wireless Personal Digital Assistants (PDAs)
- Personal or Networked Computers
- Interactive TVs
- Information Kiosks or Appliances
- Telephones
- Intelligent agents
- Any other future access device

OBJECTIVE 3: ESTABLISH HEALTH AND HEALTH CARE LEGISLATION, REGULATION AND POLICIES THAT ENSURE THE SECURITY, CONFIDENTIALITY AND SURETY OF PERSONAL HEALTH INFORMATION WHILE PROVIDING THE HEALTH CARE COMMUNITY USE OF THE HHI IN ORDER TO DELIVER HIGH-QUALITY, COST-EFFECTIVE CARE TO PATIENTS. IN ADDITION, ALLOW ACCESS TO IDENTIFIER DELETED INFORMATION TO PROMOTE EFFECTIVE HEALTH CARE MANAGEMENT, POLICY AND EDUCATIONAL PROGRAMS

Record accuracy and patient confidentiality must be ensured

HHI SECURITY, CONFIDENTIALITY AND SURETY

In an open-architecture, object-based health and health care information environment, personal health (medical record) data will increasingly proliferate. Patients’ records have traditionally been difficult to consolidate due to:

- Patient visits to organizationally distinct care facilities
- Patient movement to different geographic regions
- Expansion of health care organizations and insurers from one state to another

State laws governing medical record confidentiality are inconsistent and, in some cases, nonexistent.

OBJECTIVE 3: Establish health and health care legislation that ensures the security, confidentiality and surety of personal health information while also providing the health care community use of the HHI in order to deliver high-quality, cost-effective care to patients. In addition, allow access to identifier deleted information to promote effective health care management, policy, and education programs

Technical and/or policy attribute that drives success for this objective	Units of Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Personal health information security and surety	Encryption standards	No agreed standards across systems	Consumers & legislators converge on requirements	Test beds demonstrate security & data integrity	All electronically accessed personal (private) information secured & assured
Medical record information confidentiality & access	Confidentiality & access definitions	Inconsistent confidentiality and access regulations among States	Blue Ribbon Commission to determine confidentiality & access issues	Consistent national and statewide confidentiality & access regulations	

As a result, national legislation and regulations are required to protect the welfare of patients, providers and administrators, as well as to facilitate the legitimate objectives of health care system developers. Federal legislation should be passed to protect the confidentiality of personal health records on systems in both electronic and paper form. This legislation should protect a customer/patient’s privacy while not presenting an undue burden on health care providers and users of health care information. Further, such legislation must provide penalties for persons who misuse or improperly disclose information.

Legislation is needed to ensure record confidentiality, security and surety

Bills currently in Congress dealing with medical records privacy/protection include the following:

- S. 1360, “The Medical Records Confidentiality Act of 1995” (104th Congress)
- H.R. 435, “The Fair Health Information Practices Act of 1995” (104th Congress)
- S. 2129, “The Health Care Privacy Protection Act” (103rd Congress)

The following identify some principles to be included in needed legislation concerning health care information record security, confidentiality and surety:

- Specific requirements for system reliability and security (perhaps also the processes and qualifications of personnel responsible for operating systems)
- Protection from mistakes and inadvertent disclosure of private information
- Protection from unreasonable or erratic retrospective reviews of provider decisions and performance based on record reviews
- Reasonable protection from law enforcement agencies
- Consistent, uniform requirements and procedures for recording record disclosures, among others

OBJECTIVE 4: ESTABLISH A SYSTEMS FRAMEWORK TO IMPROVE THE TESTING AND REGULATION OF HHI SYSTEMS AND COMPONENTS

Testing and regulating HHI systems and components must be facilitated

The Food and Drug Administration (FDA) has the responsibility to ensure the safety and effectiveness of health care devices and software when applied to diagnosis and treatment. In principle, the FDA policy is “to apply the least possible regulatory action required by law to fulfill our public health responsibility.”⁸ Often, this action appears too protracted to the health care community. Correspondingly, the regulatory community has the responsibility to ensure the safety of the consumer/patient.

The National Laboratories are systems savvy and could be engaged in the regulatory testing process

In addition, the majority of previous and, to an extent, current focus of the FDA has been to address “medical devices.” As the national HHI-based systems become more physically distributed, heterogeneous, and informationally longitudinal, the effectiveness and safety considerations of individual components may be stretched beyond the FDA device and software quality control capability. In an effort to develop a framework to address these future systems and components characteristics, organizations (e.g., National Laboratories) with a long and trusted history in systems integration, safety, and effectiveness should be engaged in the regulatory testing process.

OBJECTIVE 4: Establish a systems framework to improve the testing and regulation of HHI systems and components

Technical and/or policy attribute that drives success for this objective	Units of Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
HHI software system & component safety, effectiveness & testing	System &component safety, effectiveness & testing standards	Primitive standards across systems' systems	FDA engage experienced systems' integrators (e.g., National Laboratories) on safety, effectiveness & testing requirements	FDA and systems' integrators develop cooperative, dual-use test beds	Systems' integrators operate test beds to address system & component safety & effectiveness
Health & health care information evidence-based ratings	Number & type of evidence supporting information	Evidence-based health screening recommendations	NLM leads development of evidence-based rating system	Rating system is tested and modified as needed	Rating system is made optional

TECHNOLOGY AND POLICY DRIVERS

A summarized list of the principal technologies and policies that drive the success of the above objectives is:

- OPEN-ARCHITECTURE, OBJECT-BASED COMPONENT SOFTWARE (I.E., COMPONENTWARE)* TO SERVE AS THE FOUNDATION FOR ALL HHI SUBSYSTEMS AND APPLICATIONS
- STANDARDIZED COMPONENT INTEGRATION METHODOLOGIES TO FACILITATE DEVELOPMENT OF APPLICATIONS FROM COMPONENTS
- IDENTIFICATION OF APPROPRIATE PREVENTIVE HEALTH AND COST-EFFICIENT HEALTH CARE PRACTICES AND EMPHASIS ON THEIR ADOPTION BY CONSORTIA AND THROUGH LEGISLATION

CRITICAL INFRASTRUCTURE AND CORE COMPETENCIES

The following table summarizes the list of key technology and policy drivers in addition to the systems and core competencies to which they relate.

KEY DRIVERS	SYSTEMS & CORE COMPETENCIES
Standardize open-architecture, object-based "componentware" to serve as a basis for subsystems & applications	<ul style="list-style-type: none">• Establish consortia to define HHI systems architecture• Consortia to define HHI subsystem interface standards• Consortia to define & develop health object classes• Model RFPs to mandate componentware in HHI developments• Encapsulate legacy systems• Testbeds organized to test & validate HHI systems and components
Emphasize preventive health by the management and delivery of and shared decision making in health care information & services	<ul style="list-style-type: none">• Establish preventive health principles and measures for public and private care organizations• Develop multi-media shared decision tools• Expand the range of health information services by public & private organizations
Establish legislation that ensures the security, confidentiality and surety of personal health information	<ul style="list-style-type: none">• Establish Blue Ribbon Commission to determine requirements for HHI system reliability and security

OPPORTUNITIES AND SHOWSTOPPERS

OPPORTUNITIES

• CONVERGING DEVELOPMENTS POINT TO NEW OPPORTUNITIES

Several developments including the national health care cost containment efforts and the rapid development of information networks present new opportunities for delivering healthcare information services.

• NEW HEALTH EDUCATION VENUES

New media introductions by telecommunications providers offer intriguing opportunities to reach large audiences for health education information.

• DEVELOPMENT OF FUTURE HHI SYSTEMS

Major public and private sector health care purchasers must be made aware of the significant advantages of an HHI and be persuaded to demand object-based componentware from their vendors.

• MODEL HHI FUNDING REQUIREMENTS

Public and private funding agencies that fund health informatics projects should be made aware of the significant advantages of the HHI paradigm and persuaded to demand object-based, componentware development in their funded proposals and RFPs.

• OBJECT-BASED DEVELOPMENT & TOOLS

The opportunities for object technologies and for HHI-based systems development are rapidly becoming optimal. Although object technology has been around for a long time, recent events have accelerated its progress. For example, Java⁹ is a cross-platform, object-oriented language for the development of applets distributed over networks (especially the Internet) that has gone from obscurity to a widely accepted approach within the last year. This experience has demonstrated to many the significant advantages of object technology.

More significant opportunities come from organizations working to advance object technologies and componentware. Examples include the Object Management Group (OMG)¹⁰, an industry-sponsored nonprofit consortium established in 1989 in anticipation of wide-spread object technology use to address the issues of object standards; Object Database Management Group (ODMG), a consortium of object-oriented database management system (ODBMS) vendors and interested parties working on standards to allow

Object technologies should be utilized for new HHI development

A number of organizations are working to advance object technologies and componentware

portability of customer software across ODBMS products; and CI Labs, a nonprofit industry association which adopts, licenses, validates, and registers multiplatform, distributed component software. These groups are comprised of almost all of the major and minor players in the hardware and software industries including those with significant health care information systems. These groups will have significant influence in establishing object technology for the HHI.

SHOWSTOPPERS

• UNPREDICTABLE DYNAMICS OF THE US HEALTHCARE DELIVERY SYSTEM

The integration of cutting-edge technologies coupled with the unpredictable dynamics of the US health care delivery system challenge the goal of the achieving improved health and health care quality while reducing health care cost.

• POTENTIAL INTEROPERABILITY PROBLEMS BETWEEN DISPARATE SYSTEMS

An early major show stopper would be failure to systematically guarantee interoperability between objects, i.e., more than a single standard for object messages. In other words, the continued use of proprietary, closed-architecture systems will prevent or strongly inhibit the development of object technology, in general, and HHI-based systems and subsystems and applications, specifically.

• ENSURING THE QUALITY OF INFORMATION SYSTEMS AND COMPONENTS

Another major show stopper is quality assurance. Regulatory and/or certifications processes must be developed which assure that software components have met quality standards developed and are safe for use in health and health care. At least two quality assurance strategies are needed for HHI systems:

1. One strategy would allow easy certification of nonhealthcare delivery-related software components. For example, the addition of new printer drivers, word processing, educational programs, etc. These software components would be only indirectly related to health care delivery, and their malfunction or failure would not directly threaten human life. Their functions would be no different from the products already in use in health care institutions. These products would be certified from the software reliability standpoint only.

*At least two strategies are needed
for quality assurance*

*Strategy 1: Allow easy certification
of software components*

2. The other quality assurance strategy would be regulatory approval of health care delivery-related software components. These software components are directly involved in health care delivery, and their malfunction or failure could directly endanger human life or even lead to or cause harm or death. Since the HHI will extensively underlie robotics, for example, it is essential that quality and proof of concept be assured. Like drug approvals, these software components approvals may need several phases. These phases should make extensive use of standard (approved) testbeds and simulations whenever possible and avoid expensive real-life testing. Off-line testing on real-life systems could be used prior to regulatory approval as a phase.

• POTENTIAL FOR UNRELIABLE HEALTH AND HEALTH CARE INFORMATION

Finally, confidence in and the success of HHI-based systems would be threatened by the presence of unreliable health and health care information. Consumers and providers must be confident that the information provided is reliable. Rather than instituting censorship, an evidence-based rating system of health and health care information must be established and made optional. Use of unrated information would be at the consumers' risk. How ratings were determined should be available to consumers. Only a single rating system should be established so as not to confuse consumers.

*Strategy 2: Regulatory approval
for health care delivery software
components*

*An evidence-based rating system
for health care information must
be established*

REFERENCES AND ENDNOTES

- 1 The glossary defines basic and key terms in health and health care. Words with critical conceptual definitions in the glossary are marked with an asterisk (*).
- 2 The first function of health care is more extensively developed in the table than subsequent functions. This is done to highlight the exercise rather than to suggest this function is more important than any other.
- 3 Future health and health care will be to some extent not restrained within walls and locations. For example, health care providers with necessary supplies can be dispatched to the patient's location or some other intermediate location(s) appropriate to the patient's level of need.
- 4 Harris, Linda M. *Health and the New Media*. Mahwah, NJ: Lawrence Erlbaum Associates, Publishers, 1995; page 9.
- 5 Fries, J. F., Koop, C. E., Beadle, C. E., et al., and the Health Project Consortium. *Reducing Health Care Costs by Reducing the Need and Demand for Medical Services*. New England Journal of Medicine, 1993; 329(5): 321-325.
- 6 Greenes RA, Deibel SRA. *Constructing Workstation Applications: Component Integration Strategies for a Changing Health-Care System*. IMIA Yearbook of Medical Informatics 96: (Van Bemmel JH, McCray AT, eds). Rotterdam, The Netherlands: IMIA. 1996; 76-86 (in press).
- 7 Taylor, David A. *Object-Oriented Information Systems: Planning and Implementation*. New York: John Wiley & Sons, Inc., 1992.
- 8 Young, Frank E. *Position Paper: Validation of Medical Software: Present Policy of the Food and Drug Administration*. Institution: Food and Drug Administration, Rockville, Maryland. Annals of Internal Medicine. 1987; 106(4): 628-629.
- 9 Sun Microsystems, Inc., 2550 Garcia Avenue, Mountain View, CA 94043-1100 USA
- 10 The Object Management Group, Inc., Framingham Corporate Center, 492 Old Connecticut Path, Framingham, MA USA 01701; Phone: (508)820-4300; Fax: (508)820-4303.

glossary

Without definitions, this whole effort would be folly. The following key terms mean the following when used in this document. Although possibly controversial, for purposes of this document they are definitive.

Componentware: Software subsystems and applications built using local or distributed objects.

Cost-containment: An effort by society to keep expenditures for health care to a certain percentage of gross domestic product.

Cost-effectiveness: A decision to provide or not provide health care based upon the evaluation of the health care in relation to its costs. It is a measure of society's values and limits.

Cost-efficiency: The provision of health care for the least costs without affecting quality.

Data: Any fact(s) which may generate information when knowledge is used to evaluate or manipulate it.

Health: The total physical, mental and social well-being of a person and not just the absence of disease or infirmity. (World Health Organization)

Health Care: Anything that deals with health, disease or infirmity.

Health Care Costs (Total): The sum equals the direct economic (DE) costs plus indirect economic (IE) costs plus costs to human life (HL) plus the costs of human pain and suffering (HPS).

$$HC(T) = DE + IE + HL + HPS$$

Direct economic costs are those funds expended directly for paying for health care (including insurance premiums, health maintenance/preventive medicine costs).

Indirect economic costs are those economic costs incurred due to the lost of health. This includes losses due to sick days paid and/or to loss productivity incurred due to the worker's loss of health. The costs of replacing the worker who has loss of health are included.

Costs of human life are the loss of human lives (mortality) incurred directly by the provision of health care.

Costs of human pain and suffering are the pain and suffering (morbidity) to the patient/client and significant other(s) incurred directly from the provision of health care.

Informatics: The discovery, integration, application and teaching of information including its generation and dissemination for optimal use.

Information: Data evaluated using the appropriate knowledge generates information. Information has enhanced insight, understanding or even, generates new knowledge when compared to data. Information usually has decision-making ramifications.

Knowledge: The processes required to recognize and distinguish between data and information and the processes that manipulate data to generate information.

Objects: Objects are software entities that contain related data and procedures and respond to a set of messages.

Quality of Health Care: The quality of health care has the following four parameters:

1. The health care provided is warranted for the patient's/client's general and specific health condition(s)
2. This health care must minimize risk(s) to the patient/client
3. This health care is cost efficient
4. The patient's/client's expectations are met without violating the parameters above

Robotics: In health care, an assemblage with a monitor(s) and evaluation (afferent) and response (efferent) feedback systems. For example, a blood glucose sensor with a processor that evaluates the glucose and infuses insulin according to the glucose level would be a robotics device. Continuous feedback would allow for individual algorithm generation.

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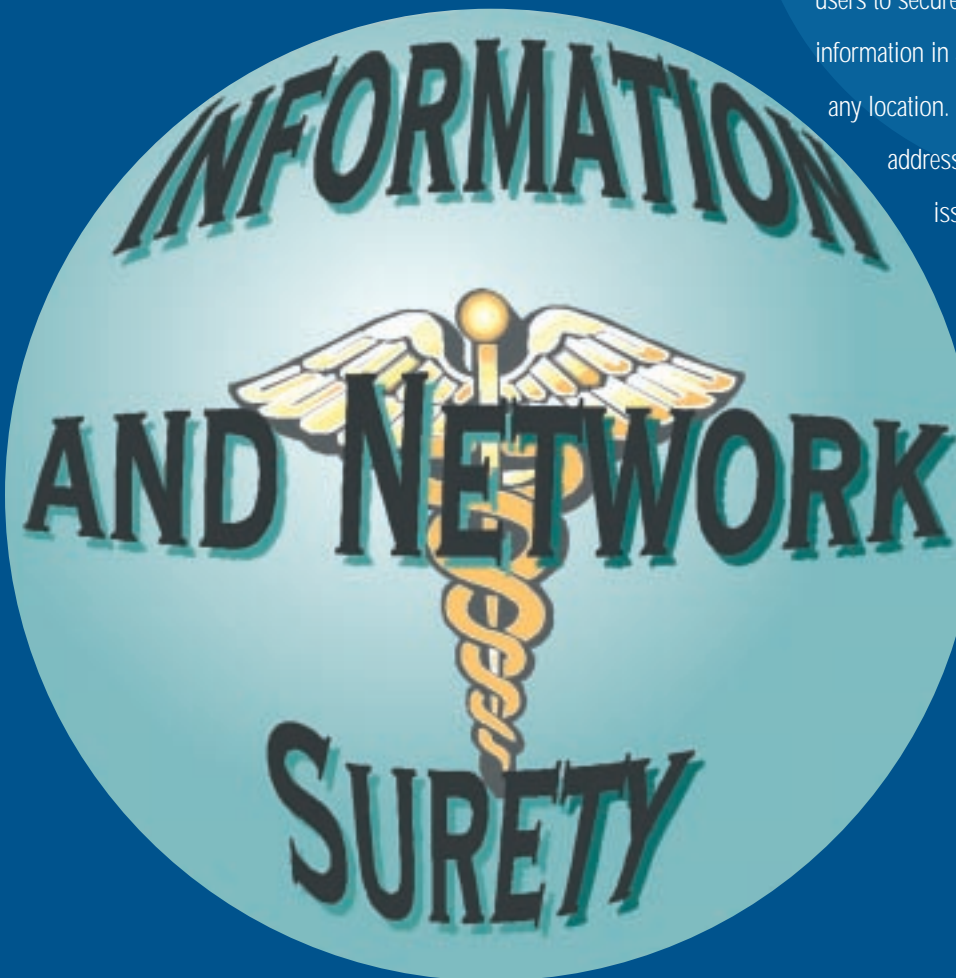
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table a

1. AID TO HEALTH AND HEALTH CARE OF THE INDIVIDUAL	1.2. Preventive Medicine/Health Maintenance	3. AID TO HEALTH CARE POLICY FORMULATION
1.1. Episodes of Care	1.2.1. Disease prevention	3.1. Outcomes Research
1.1.1. Initial Presentation	1.2.1.1. Behavior Modifications	3.2. Experimental Research
1.1.1.1. Initial History/Complaints	1.2.1.2. Interventions:	3.3. Cost Containment and Cost Effectiveness Policy
1.1.1.2. Physical Examination	1.2.2. Early detection screening	
1.1.1.3. Diagnostic Testing/Monitoring		
1.1.1.3.1. Imaging		4. AID TO HEALTH CARE EDUCATION
1.1.1.3.1.1. Physician performed	2. AID TO HEALTH CARE PROVIDER MANAGEMENT	4.1. Medical
1.1.1.3.1.2. Technician performed	2.1. Financial	4.2. Nursing
1.1.1.3.2. Laboratory	2.1.1. Direct Care of the Patient	4.3. Allied Health
1.1.1.3.2.1. Physician performed	2.1.1.1. Licensed Staff	
1.1.1.3.2.2. Technician performed	2.1.1.1.1. Physicians	
1.1.1.3.3. Physiologic Tests	2.1.1.1.2. Nursing	
1.1.1.3.3.1. Physician performed	2.1.1.1.3. Allied Health	
1.1.1.3.3.2. Technician performed	2.1.1.2. Non-Licensed Staff	
1.1.1.4. Diagnosis	2.1.2. Indirect Care of the Patient	
1.1.1.4.1. Severity Scoring	2.1.2.1. Personnel	
1.1.1.4.2. Prognostication	2.1.2.2. Facilities	
1.1.1.5. Treatment	2.1.2.3. Administration	
1.1.2. Subsequent Care		
1.1.2.1. Interval History/Complaints	2.2. Administration	
1.1.2.2. Interval Physical Examination	2.3. Practice Management	
1.1.2.3. Interval Testing and Monitoring	2.3.1. Guidelines Formulations/Implementation	
1.1.2.4. Treatment Monitoring	2.3.2. Continuous Quality Improvement/Cost efficiency Research	
1.1.2.4.1. Compliance monitoring	2.3.3. Practice Variation Evaluations	
1.1.2.4.2. Side Effects/Complication monitoring		
1.1.3. Patient/Client Education	2.4. Public Health	
1.1.3.1. Health		
1.1.3.2. Disease/Infirmary		
1.1.3.3. Health Care		

INFORMATION AND NETWORK SURETY TECHNOLOGY ROADMAP

The future US health care information infrastructure will be developed as a distributed heterogeneous network of consumers and services. In this networked environment, one of the principal requirements will be the ability for users to securely input and access health information in any media form, at any time and from any location. Much of the technology needed to address the information and network surety issues for electronic health information systems exists today and some general products are available. The following Technology and Policy Roadmap addresses the minimal surety requirements for the successful development and deployment of health information systems over the next 15 years.



DESCRIPTION

Effective authentication, audit processes, and actions for misuse are required

In order to place this Roadmap in the proper context, a vision for the end system needs to be articulated. The overarching objective of this Roadmap effort is:

Health information should be accessible over public networks and from multiple vendor platforms, with appropriate protection of individual privacy and data integrity. Access should be controlled through effective authentication and audit processes, with appropriate sanctions for misuse. Expected gains are improved health care, increased access to care and cost savings.

HEALTH INFORMATION AND NETWORK SURETY EFFORTS

Confidentiality is paramount

Sandia National Laboratories hosted the Biomedical Prosperity Games as the initial event in an approach to address the identification of technology and policy roles in the future of US health care delivery needs. The Game brought together various stakeholders with expertise in the broad spectrum of health care technologies. Complex health care issues were examined in a variety of economic, political and social scenarios. One of the principal results of the Game was the identification of the need for protecting health information.

Various standards organizations are addressing security issues

Many other groups have addressed information security issues related to electronic health information, especially patient records, as evidenced by the long list of security resources for electronic health information in the Medical Record Institute's February 1996 newsletter (Toward An Electronic Patient Record, Volume 4, Issue 7). Included in this list are standards bodies such as the American Society for Testing of Materials (ASTM) E31 on Health Care Informatics, which is one of the leading standards organizations for security issues regarding health information.

The list of resources also includes publications by various organizations such as the Institute of Medicine (IOM) of the National Academy of Sciences, the Congressional Office of Technology Assessment (OTA), and the American Health Information Management Association (AHIMA). Reports by these organizations have:

- Articulated the high-level needs of a broad spectrum of stakeholders
- Identified major privacy issues
- Exposed policy inadequacies

- Enumerated problems with current paper and electronic health record systems
- Proposed a variety of solutions

Despite the efforts of these organizations, there remains substantial disagreement on privacy issues related to electronic health information systems. The various stakeholders agree, however, on the need for better definition of the security requirements for electronic health information systems. Because of the diversity of interests of stakeholders and needs of health information system users, however, it is possible that even the high-level requirements of the different stakeholders will be in conflict with one another.

UNIQUE APPROACH

This Roadmap effort addresses not only security, but the surety needs for electronic health information systems as well. Sandia National Laboratories uses the term information surety to refer to balancing confidentiality (or privacy), integrity, and availability of data. In other words, information surety refers to the balance between protection against unauthorized use of information and assurance of authorized use. By contrast, the term information security connotes an emphasis on protection against unauthorized use of information. The term network surety refers to the surety of information in its delivery across a network.

This Roadmap will address privacy issues related to electronic health information and address the issues related to data integrity and availability. The issues that will be addressed are:

- Determine whether the user of a system is who he claims to be
- Ensure that the data is not changed or accessed by an unauthorized action or user
- Ensure that the data is not changed by accidental means
- Ensure that the data cannot be refuted
- Determine when the data was created or modified
- Determine who created or modified the data
- Determine when the data was accessed
- Determine who was granted what access by the system
- Ensure that the data will be available and useable when needed

Much of the technology needed to address the information and network surety issues for electronic health information systems exists today and some surety products are already available. However,

A better definition of security requirements for information systems is needed

This Roadmap addresses security and surety for health and health care information systems

There are a number of privacy issues related to an electronic health information system

A consensus on requirements must be reached to take advantage of available technology

these products seldom interoperate and quite often are not adequately customized to meet the exact needs of the health care community. Since there is little agreement among various stakeholders about even a minimal set of information surety requirements for these systems, only piecemeal solutions have emerged. If the stakeholders can reach consensus on basic requirements for health information and network surety, they can drive the information technology market to create the products required. The stakeholders also need to reach consensus on the priority of these requirements to allow the health care industry to introduce in a logical and orderly manner information and network surety technologies and to establish the infrastructure to accommodate them. Without agreement on the priority of these requirements, systems that are developed will not adequately satisfy all stakeholder needs. The following Roadmap represents a first step in resolving these and other health information and network surety problems.

TECHNOLOGY AND POLICY OBJECTIVES

The objectives over the next 15 years to address the vision are:

- 1. DEVELOP DATA AND NETWORK SECURITY MECHANISMS AND PRODUCTS TO PROVIDE APPROPRIATE PROTECTION OF INDIVIDUAL PRIVACY IN ELECTRONIC HEALTH INFORMATION APPLICATIONS. DEVELOP TECHNOLOGY TO PROMOTE EFFECTIVE AUTHENTICATION AND AUDIT PROCESSES**
- 2. DEVELOP TECHNOLOGIES AND PRODUCTS TO IMPROVE DATA INTEGRITY DURING GENERATION, TRANSLATION, TRANSPORTATION, AND STORAGE**
- 3. DEVELOP, IMPLEMENT AND REGULATE STANDARDS FOR INFORMATION SURETY MECHANISMS REQUIRED BY THE HEALTH AND HEALTH CARE COMMUNITY TO ALLOW THE CREATION OF INTEROPERABLE SURETY MECHANISMS**

TECHNOLOGY AND POLICY ROADMAPS

A list of the requirements and drivers that are necessary to meet the objectives in the near (0 to 3 years), intermediate (3 to 6 years) and far (6 to 15 years) term are presented in the tables that follow.

OBJECTIVE 1: DEVELOP DATA AND NETWORK SECURITY MECHANISMS AND PRODUCTS TO PROVIDE APPROPRIATE PROTECTION OF INDIVIDUAL PRIVACY IN ELECTRONIC HEALTH INFORMATION APPLICATIONS. DEVELOP TECHNOLOGY TO PROMOTE EFFECTIVE AUTHENTICATION AND AUDIT PROCESSES

As indicated in the Objective 1 table, there are many technical attributes that will drive the success of this objective:

There are a number of technical attributes that address successful data and network security

- Standardized classification and organization of data
- Effective authentication of end users, including the roles of users
- Effective access controls based on the roles of participants
- Effective data authentication techniques
- Effective audit mechanisms and policies
- Encryption
- Surety of wired and wireless communications
- Key management

STANDARDIZED CLASSIFICATION AND ORGANIZATION OF DATA

Certain issues concerning access to health information must be addressed

To provide appropriate protection for individual privacy with regard to electronic health information, access to the information must be controlled. When discussing access issues in information surety, the following questions must be answered:

- Who needs access?
- What data needs to be accessed?
- What kind of access do users need?

OBJECTIVE 1: Develop data and network security mechanisms and products to provide appropriate protection of individual privacy in electronic health information applications. Develop technology to promote effective authentication and audit processes

Technical and/or policy attribute that drives success for this objective	Units of Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Standardized organization and classification of data	<ul style="list-style-type: none">• Data organization that is sufficiently fine-grained to meet the needs of all stakeholders	<ul style="list-style-type: none">• No standards• Little agreement in community• Database designs are proprietary	<ul style="list-style-type: none">• Definition of unique personal identifier• Standrds for database organizations• Standards for data sensitivity labeling• Standards for data latency	<ul style="list-style-type: none">• Implementation of unique personal identifier• Standards to support transfer of records between disparate systems	<ul style="list-style-type: none">• Mechanisms to address solution to inference and aggregation problems• Standardized portable patient copy of longitudinal record to serve as a backup copy
Effective authentication of end users, including roles of users	<ul style="list-style-type: none">• User acceptable methods• Does not slow delivery of health care treatment• Have emergency by-pass with audit mechanisms	<ul style="list-style-type: none">• Passwords	<ul style="list-style-type: none">• Introduction of biometric identification devices in critical user ID environments• Widespread use of tokens	<ul style="list-style-type: none">• Positive identification and authentication of all principals and roles• Biometric applications of broader scope• Widespread use of smart tokens	<ul style="list-style-type: none">• Cryptographically secure use of biometrics• Proximity based biometric based ID
Effective access controls based on roles of participants	<ul style="list-style-type: none">• Transferable in a highly distributed environment• Ability to distinguish roles even for same user	<ul style="list-style-type: none">• Access matrices manually maintained by local system administrators	<ul style="list-style-type: none">• Centrally-managed, fine-grained access control (e.g., currently, a database administrator sets up access control	<ul style="list-style-type: none">• Flexible distributed fine-grained access controls• Delegation of authorization for some users• Development of flexible policy management protocols	<ul style="list-style-type: none">• Improved computer operating system techniques for access controls• Negotiation of access control between disparate systems (control foreign users; foreign users entering another domain)• Nationwide policy for access control
Effective data authentication techniques	<ul style="list-style-type: none">• Non-refundable• Minimal effects on performance	<ul style="list-style-type: none">• Products appearing now• Legal issues not resolved and key and certificate management not in place	<ul style="list-style-type: none">• Digital signatures• Legislation to define enforceability of digital signatures	<ul style="list-style-type: none">• Development of scaleable, robust, agile authentication protocols	<ul style="list-style-type: none">• Widespread deployment of digital signatures to authenticate systems, data and authors
Effective audit mechanisms	<ul style="list-style-type: none">• Non-refundable• Manageable (not just reams of data)	<ul style="list-style-type: none">• Some products available	<ul style="list-style-type: none">• Ad hoc and proprietary audit trails	<ul style="list-style-type: none">• Legal guidelines for auditable events• Minimal proactive audit processes• Secure time-stamping	<ul style="list-style-type: none">• Developmet of high speed, efficient auto-mated audit reports• Comprehensive audit processes
Encryption	<ul style="list-style-type: none">• Scaleable-strength, speed, multiple channels	<ul style="list-style-type: none">• Basic products available• Export controls slowing development	<ul style="list-style-type: none">• Resolution of encryption export controls• Availability of software encryption APIs in operating systems	<ul style="list-style-type: none">• Acceptable standard public algorithms	<ul style="list-style-type: none">• Ubiquitous network encryption
Surety of wired and wireless communications	<ul style="list-style-type: none">• Support for real time data• Interoperable, reliable, and available	<ul style="list-style-type: none">• Single channel link and end-to-end encryptors	<ul style="list-style-type: none">• Multi-channel end-to-end encryptors• OC-3 ATM encryptors• End-to-end network authentication	<ul style="list-style-type: none">• Multi-channel robustness agile encryptors• Wireless ATM networks• Improve end-to-end authentication• Network route authentication mechanisms• Increased reliability of wide area networks	<ul style="list-style-type: none">• Wide area (Satellite) wireless networks• Network threat Response Systems• Improved firewall technologies for access control
Key Management	<ul style="list-style-type: none">• Highly distributed• Reasonable• Trusted• Easy compromise-recovery	<ul style="list-style-type: none">• Not much outside of local, custom handling	<ul style="list-style-type: none">• Local public key infrastructure• Smart tokens	<ul style="list-style-type: none">• National public key hierarchy for users and nodes• Key escrow for data archival and recovery	<ul style="list-style-type: none">• International agreements on PKI

Sensitivity levels of health data must be defined

To adequately answer these questions, health data elements must be defined, including their sensitivity levels. The definition of sensitivity levels of data elements help answer the question as to who should have access to the data element and what kind of access they should have.

National standards that include a definition for a personal identifier must be put in place

To ensure that health data can be shared by disparate systems while maintaining sensitivity levels, national standards for data organization and classification must be developed and accepted. Included in this standard should be the definition of the unique personal identifier. Any standard developed must also be able to efficiently accommodate changes that will inevitably occur. Examples of such changes are the introduction of new data elements and the modification of sensitivity levels.

In addition to labeling data according to its sensitivity, the latency of data must also be standardized. Health information components have unique storage and retrieval requirements. Some information must be accessible in real time, while other information can be archived with the retrieval time requirement relaxed.

The health care community can leverage the defense community for surety solutions

Entries in a database may individually be nonsensitive. However, when viewed as an aggregate, sensitive information may be inferred. This is a problem which has been and will continue to be studied by the defense community. Some products exist to help with this problem; however, complete solutions will likely not be found in the near future. For the near term, mechanisms can be put in place to make it more difficult to gain information through inference or aggregation. The health care community can leverage the efforts of the defense community in solving the database inference and aggregation problems.

EFFECTIVE AUTHENTICATION OF END USERS AND ACCESS CONTROLS***The health information system must positively identify an individual and the individual's role***

Strong authentication of end users and their roles focuses on the ability of the health information system to successfully and positively identify a user of the system located anywhere on any machine. Problems and issues associated with positive identification and authentication are false negatives, false positives, the protection of the identification and authentication devices themselves, and the protection of the communication between such devices and the system. The ability to tamper with the identity device or insert a valid authentication data stream, allows an invalid user to be wrongly identified by the system as a valid user. To successfully evaluate the roles of individuals, the system must first positively identify the individual and associate the individual with the specified role. The system must contain the proper information about the role of the individual, including the policies governing the individuals access to information and valid actions that the individual may take on the data. Such actions include viewing, appending, and correcting information in a file.

EFFECTIVE DATA AUTHENTICATION TECHNIQUES

Data authentication involves the verification of the integrity of the data and of the origination of the data. A mechanism must be in place to allow the user of a system to verify the system is indeed the desired system, not a unauthorized copy, and that the information obtained from that system is capable of being authenticated to the originator.

Verification addresses the origination and the integrity of the data

EFFECTIVE AUDIT MECHANISMS AND POLICIES

Audit mechanisms are one of the most important security mechanisms. When implemented properly and securely, these mechanisms allow the tracking of who accessed what information in the system and when. Note that access to information includes reading, appending, generating, modifying, or deleting information. With proper reliability, this mechanism could be used in court as evidence of proper (or improper) handling of health information. In fact, the very existence of audit trails often serves as a deterrent for the mishandling of information. The audit trail is an appealing technology since it minimizes reliance on trusted users. Today's systems require that audit trail data be accessible to system administrators and system security administrators, who are generally considered trusted users. Means must be developed to protect the audit trail from abuse by these users.

Audit mechanisms track information access

It is also necessary to record the time at which an entry was made in the audit trail so that the audit trail cannot be changed later. If the date of an action is simply entered into the audit trail, then this date can later be changed like any other piece of information, unless proper cryptographic techniques are applied to prevent such changes. This is particularly important for electronic information in legal environments.

ENCRYPTION

Encryption is used to hide information by scrambling the information into an unrecognizable form which, with the right key, can later be retrieved. The primary use of encryption is to protect privacy of information including the key information itself.

Encryption can be used to protect information

SURETY OF WIRED AND WIRELESS COMMUNICATIONS

Health information networks will stimulate the transition of health information systems from proprietary, stand-alone systems to distributed computing and storage systems. These networks will be composed of both wired and wireless components to support the diverse operational environments of the health care community.

The operational requirements for the health care industry will require the use of both fixed and mobile

Both fixed and mobile networks will require security measures

networking. Wired networks within a hospital will be used to support the administrative, general medical, telemedicine, and training reference material needs of this community, while the wireless networks in hospitals will be used to support nursing and physician needs for patient information during rounds and emergency/disaster response. The data needed to support these functions will clearly require that these networks be secure. The technologies needed to support network surety of the health care industry includes multi-channel encryption to allow individual encrypted channels for each user. In addition, flexible network encryption technologies will be needed to support high-speed networks as well as variations of algorithm robustness required by specific users or data types.

Mobile networks will require improved firewall technologies and supporting protocols

Since wireless technologies will become prevalent for mobility reasons, surety features for wireless networks must be developed for data integrity and privacy reasons. The need for improved firewall technologies must be addressed to provide better protection from outside access (i.e., assure only valid users can enter the network domain). Support for all surety will require that supporting protocols for low latency transmission, improved data integrity and automatic rerouting be developed. Finally, reliability assessment tools and architectures that provide better reliability and threat/intrusion response systems must be developed.

KEY MANAGEMENT

Poor key management can overwhelm a system

As soon as any cryptographic technique is used, key management becomes a problem. Key management is the management of the cryptographic key lifecycle: generation, certification, distribution/exchange, verification, storage, revocation, and expiration. Portable, flexible, and extensible key management techniques must be developed. If addressed poorly, key management problems often overwhelm the rest of the system. In many systems today, the algorithms that protect the data are sound in their implementation. However, weak key management allows for defeat of the system. Significant work needs to be done in this area to support a national and international public key infrastructure that is sound and supports the health care community needs.

OBJECTIVE 2: DEVELOP TECHNOLOGIES AND PRODUCTS TO IMPROVE DATA INTEGRITY DURING GENERATION, TRANSLATION, TRANSPORTATION, AND STORAGE

One of the major surety issues in any information system is the integrity of the data. The integrity of data must be protected during its entire lifecycle: generation, translation, transportation, and storage. There are several areas in which technologies and products can improve the protection of data to ensure its integrity throughout its lifecycle. These areas are:

- Data entry systems
- Representation of data in system
- Reliability of long term, large scale data storage
- Data retrieval mechanisms
- Network technology performance
- Reliability of network operations

While this Roadmap addresses the surety issues for electronic health information, many of these issues are valid for paper systems today. There will be additional issues associated with the transition from paper to electronic formats that are not covered in this Roadmap.

DATA ENTRY SYSTEMS

To improve surety during data entry, an individual needs to provide information in the most natural way for that situation. For example, the system needs to be able to support pen entries, written entries, typed entries, voice entries, video entries, and analog and digital data entries as required. The need for such a diverse set of entry mechanisms is driven by the diverse set of information that is required to be recorded. In addition to supporting data entry, the system needs to support native data storage. That is, whenever possible, a digitized version of the original object should be stored. Translation to other formats will also be discussed, but the original version should be stored to maintain as much fidelity as possible. This does several things to support the health care community: 1) it assures that there are data entry mechanisms to support the needs of all providers; 2) it retains data in the original format for review by the health care providers and supports the legal community in disputes; and 3) it retains the fidelity of the information.

Integrity of data must be ensured throughout its lifecycle

Surety of the information system requires flexibility of data entry and native data storage

OBJECTIVE 2: Develop technologies and products to improve data integrity during generation, translation, transportation, and storage

Technical and/or policy attribute that drives success for this objective	Units of Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Improved data entry systems to reduce the number of handlers of health information	<ul style="list-style-type: none">• Reduction of the number of handlers of health information	<ul style="list-style-type: none">• Pen based systems are common• Voice entry systems beginning to appear• Transcription services for taped records is most common	<ul style="list-style-type: none">• Voice entry systems• Pen-based entry systems	<ul style="list-style-type: none">• Enhanced voice entry systems• Enhanced pen-based entry systems• Beginning of direct monitoring device data entry	<ul style="list-style-type: none">• Direct monitoring device data entry based on physician guidelines
Improved representation of data in system implementation to allow for preservation of native computer formats while attaining efficient translation. This includes the mechanism for implementation of surety features	<ul style="list-style-type: none">• Extensibility• Portability• Interoperability	<ul style="list-style-type: none">• Object Oriented (OO) approaches becoming common	<ul style="list-style-type: none">• Secure objects• OO Data bases for storage of multi-media information	<ul style="list-style-type: none">• Security of intelligent agents• Early development of real-time data object translators• Improved OO data base technology	<ul style="list-style-type: none">• Objects that are secure• Security objects• Intelligent data object translators
Improved reliability of long term, large scale data storage	<ul style="list-style-type: none">• Ability to archive huge quantities of information for long periods of time, while provideng real-time access to critical care information	<ul style="list-style-type: none">• Tera-byte storage systems• Write Once Read Many (WORM) storage• Very limited deployment at present, but much has been developed in the government's HPCC program	<ul style="list-style-type: none">• Increased storage capacity/ data compression algorithms• Focus on volatility of storage media for 100+ year storage• Hierarchical storage systems using RAID and SCSI tape drives• Large facilities using technologies adapted from HPCC program	<ul style="list-style-type: none">• Meta computing• Peta-byte (10¹⁵) storage systems• Improve processes of long-term storage systems• Expensive large-scale redundant storage sites using tape/CD robots• Long term storage technologies that combine high reliability and high density (e.g., HDROM)	<ul style="list-style-type: none">• Storage systems holding up to 10¹⁸ bytes• Access controlled read/write storage systems• Introduction of non-mechanical technologies for storage, including holographic molecular storage devices• Nonvolatile RAM used for storage of critical care information (for instant fetching of data)
Improved data retrieval mechanisms	<ul style="list-style-type: none">• Ability to retieve from large-scale heterogeneous environments• Ability to retrieve all data on an individual from all sites, with critical data available quickly	<ul style="list-style-type: none">• Paper• Few isolated electronic systems, using a wide variety of disk and/or tape technologies• No central registries for locating data	<ul style="list-style-type: none">• Incompatible institutional directories to locate information• Proprietary methods of search and indexing	<ul style="list-style-type: none">• Regional directories to location information• Introduction of intelligent agents• Standards for indexing information from heterogeneous environments	<ul style="list-style-type: none">• National and internal directories• Secure intelligent agents to locate information• Automatic migration processes and software to manage information archiving• Data mining sites used for national epidemiological studies
Improved network technology performance	<ul style="list-style-type: none">• Ability to retrieve large quantities of information to remote sites without network delay	<ul style="list-style-type: none">• Interfaced multi-disk storage and retrieval schemes using the HiPPI protocol• Local area networks using Ethernet, token ring, or frame relay• Many sites not networked at all	<ul style="list-style-type: none">• Improved I/O protocols and electronics (ATM OC-24 >1Gb/s transfer rates)• Use of existing telephone networks• Increased use of ISDN and ATM/Sonet OC3 to connect sites	<ul style="list-style-type: none">• Higher speed I/O (ATM OC-196>10Gb/s transfer rates)• Wider use of dedicated wireless networks• Many sites install fiber and copper• Use of public networks via firewalls to link regions• Wide area regional networks built with ATM/Sonet OC12 and higher• National backbone uses ATM OC/48 or higher	<ul style="list-style-type: none">• Ubiquitous networking to every inhabitable structure• Increased use of satellite networks for emergency treatment (e.g., if you have an earthquake in California, you could lose your land-based network)• Flexible wireless networks
Improved reliability of network operations	<ul style="list-style-type: none">• Redundant networks capable of withstanding natural disasters and peak demands	<ul style="list-style-type: none">• Dependent on vendor and cost of equipment• Very little redundancy• Backbone internet capable of routing around some faults	<ul style="list-style-type: none">• Network Route authentication• Fiber based communications• Improved network intrusion detection• More robust wireless network protocols are required• Where networking exists, it will be a single point of failure• Increased use of switched technology erodes reliability	<ul style="list-style-type: none">• Continued growth in fiber based communications• Improvements in switching electronics• Develop priority data congestion control mechanisms• Combination of local switching with routing along multiole paths resurges as we come to depend on networks• Development of flexible wireless networks• Emerging standards for "quality of service" to support priority for critical health information	<ul style="list-style-type: none">• Improved network switching protocols and equipment• Network architecture development tools to help assure proper design and development• Combination of multiple land-based lines, flexible wireless local networks, and satellite communications provides better reliability• Widely recognized prioritization of traffic with automatic billing over arbitrary networks

REPRESENTATION OF DATA IN SYSTEM

Data translation technologies will also be needed. For example, converting handwritten or verbal inputs to typed or ASCII characters may facilitate later use. Although the need to translate formats exists; the need to assure that the information maintains its accuracy is also required. Today this translation is done by clerks with review by the actual care giver. This is both error prone and raises the issue of the clerks' access to possibly sensitive information.

Data may need to be translated, but the accuracy of information must be retained

RELIABILITY OF LONG TERM, LARGE SCALE DATA STORAGE

Both data storage and retrieval mechanisms are very important to the success of electronic health information. The requirements for data retention in the health care community need to be defined. The health care community may need technologies to support 100+ year retention capability as well as high storage densities (10¹⁸ and beyond). From a surety point of view, reliability of data storage and the performance issues in data storage and retrieval are critical considerations for the timely delivery of data. The focus must be on retaining the information, not on the media or technology used to retain the data.

Data storage and retrieval systems are important, and requirements must be defined

There are generally two types of data that must be considered when discussing data storage and retrieval: 1) data that must be accessible in real time, and 2) data that can be archived and can withstand delays in retrieval time. Different types of data have different reliability and performance requirements. Hierarchical storage systems address these issues by addressing the staging of data.

Hierarchical storage systems help stage the different types of data

In the intermediate term, large-scale redundant storage sites using technologies such as tape or CD robots will be expensive because there will not be an immediate mass market. However, with the current trend of mechanical storage density doubling while storage costs are cut in half every three years, such storage sites will become affordable.

DATA RETRIEVAL MECHANISMS

Once data is stored, the first task of data retrieval mechanisms is to locate the data. It is envisioned that health information data will be distributed and dispersed across heterogeneous environments in various locations. Therefore, there must be central registries and directories for locating data with standard methods for searching and indexing of data. Since these registries and directories will hold or point to sensitive information, they must be carefully protected. The labeling of data as to its sensitivity and latency will be necessary for efficient searching and indexing and for effective access control.

Central registries and directories with standard methods for searching and indexing are required

*Registries and directories must
be updated to reflect changes
in record location*

The relative value or access need for information changes over time. Processes must be put in place such that information can be archived appropriately and in a timely manner. For example, when a person dies his records will seldom be accessed so that archival of his records is appropriate. This archiving will require that the registries and directories be updated to reflect the new location(s) of the records. Software will need to be developed to automatically collect the records, store them in the new location(s), and update the registries and directories.

Technologies will be needed to retrieve data from various locations and integrate into comprehensible information. Intelligent agent technology can provide such functionality; however, the agents themselves must be made secure.

NETWORK TECHNOLOGY PERFORMANCE

Higher speed networks are needed

Currently, most communication rates (some long-haul lines excluded) are limited to a bandwidth of 622Mb/s. In addition, the supporting transport protocols carry a large process and latency overhead.

*Applications of current technologies
can address some bandwidth
requirements*

Higher-speed networks that operate at greater than 10 gigabits per second and supporting light-weight protocols are needed to improve network performance. Native mode asynchronous transfer mode (ATM) possesses excellent characteristics to support networks with these features. Improving the base infrastructure and providing digital communication via integrated services digital network (ISDN) services to the desktop are important initial capabilities. The price of fiber and type-5 copper services to the desktop must be reduced to support the local area infrastructure. In addition, follow-on capabilities should include services such as ATM to the desktop with bandwidth-on-demand capabilities.

*Satellite networks can support
emergency treatment needs and
transglobal communications*

A long-term goal is the use of satellite networks to support emergency treatment needs and infrastructure redundancy needs. The ability to support flexible wireless or ad hoc networks will become critical to assure ubiquitous networking anywhere at any time. This will support the ultimate need for health care information in disaster response, rural health care and remote trauma support situations. It will also enable specialists to consult from anywhere in the world.

RELIABILITY OF NETWORK OPERATIONS

Route authentication, fiber-based interconnections, priority data congestion protocols, and network switching protocols must be improved to advance network surety:

- Route authentication provides a means of assuring the switching network is a trusted device and not a device that is added to the network by an adversary.
- Fiber based interconnects provide greater communications security, robustness, and transmission reliability. The fiber media is also difficult to splice without detection.
- Priority data congestion protocols assure that critical/emergency information will transfer during heavy network loads and provide an assured channel where denial of service attacks are attempted.
- Improved network switching protocols assure high-speed, robust, ubiquitous network communications anytime, anywhere. Network switching protocols for ATM and wireless ATM are beginning to be developed.

Protocols to address the security, reliability, integrity, and availability of data must be developed to support mobile communications for care providers.

*Improved network operations are
required for network surety*

*Protocols are needed to support
mobile communications*

OBJECTIVE 3: DEVELOP, IMPLEMENT AND REGULATE STANDARDS FOR INFORMATION SURETY MECHANISMS REQUIRED BY THE HEALTH AND HEALTH CARE COMMUNITY TO ALLOW THE CREATION OF INTEROPERABLE SURETY MECHANISMS

Standards are being developed for the health care community and all layers of computing systems

Many efforts are currently underway to address health information standards. In addition to standards developed specifically for the health and health care community, standards are also being developed for the lower layers of computing systems (e.g., network layer). These low layer standards will be used by many industries, including healthcare. A coordinated effort among all of the standards bodies is needed to ensure that each of the standards for all layers of network computing are interoperable and compatible.

Measures of the effectiveness of information surety in information systems have long been a dream of the DoD. The Defense Department has developed a methodology for design and evaluation of INFOSEC products that defines features that may be required to ensure proper handling of sensitive information by computers. The Rainbow Series, referring to the colors of the covers for the booklets, describe various aspects of this process. The biggest downfall of this system is that evaluation of products developed to these specifications has been too slow for the fast paced developments in information technologies today. The broader health community needs to develop a less stringent approach and a streamlined process for assessing the effectiveness of health information system surety measures.

A comprehensive set of guidelines and a new governing body are needed for the development and enforcement of surety requirements

Although there are many accreditation bodies for the health care industry, there is not a centralized governing body for the development and enforcement of health information surety requirements. Rules provided by each agency provide good guidance, although they may not necessarily be consistent with guidance from other accrediting organizations or cover all areas of concern. To assure that a comprehensive set of guidelines is developed, a survey of existing approaches should be conducted with the goal to develop a single best practices approach. In addition, a new governing body should be established to expand on these guidelines and standards. Further, mechanisms and policies governing revision control should also be developed and administered by this new organization.

OBJECTIVE 3: Develop, implement, and regulate standards for information surety mechanisms needed by the health and health care community to allow the creation of interoperable surety mechanisms

Technical and/or policy attribute that drives success for this objective	Units of Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Development of standards to allow systems to inter-operate and for data to be shared between systems	Development of standards for messaging interfaces, health code sets, data organization, data classification, minimal audits, consent mechanisms, access views for electronic health information, and inter-operability of security mechanisms	Several standards bodies supporting such areas as HL7 codes, electronic data interchange, ASTM, etc.	Focus on EDI for medical community Standards for different types of data, such as immunization data and emergency data	Definition of national standards for health information Definition of inter-national standards for health information	Acceptance and ubiquitous usage of national and international standards for health information Vendors compete on features but do not captivate the users (i.e., do not lock them into a proprietary solution)
Evaluation of the effectiveness of surety standards and implementations	Development of measures of effectiveness of surety mechanisms and systems to include technologies, processes and practices. These measures must support legal and policy standards.	Ad hoc and mostly aimed at recognition of problems Relative strengths of algorithms known	Develop standard surety terminology, things to measure and methods for measurement Must avoid government rainbow series evaluation pitfalls; i.e., time for evaluation is greater than product development cycle	Develop tools to support evaluation efforts Improved sure design methodologies Develop tools to support sure system design	Development of off the shelf system components available for plug and play of sure elements
Creation of a governing body to approve and accredit	Accreditation must be addressed in a uniform manner rather than separate agencies using different and perhaps competing accreditations requirements for surety	Many agencies (e.g., JCAHO, HCFA, NCQA) approve and accredit in some areas of surety. Not much coordination and no real standards for security elements today	Survey and incorporate current approaches to find the best practices known Expand incorporate developing evaluation standards mentioned above Protocols for revision control Definition of revision control policies Accountability for what happens to records	Single, over-arching committee that guides surety technology insertion and legal policy revisions Revision control infrastructure	

TECHNOLOGY AND POLICY DRIVERS

A summarized list of the principal technologies and technology-related policies that drive the success of the objectives are:

- **A NATIONALLY ACCEPTED, PRIORITIZED SET OF SURETY REQUIREMENTS FOR ELECTRONIC HEALTH INFORMATION MUST BE DEFINE. WITH THESE REQUIREMENTS, THE INFORMATION TECHNOLOGY INDUSTRY WILL BE ABLE TO DEVELOP PRODUCTS THAT MAKE THE VISION A REALITY**
- **A STRONG PARTNERSHIP BETWEEN SURETY TECHNOLOGISTS AND POLICY MAKERS MUST BE FORMED IN ORDER TO PRODUCE EFFECTIVE LEGISLATION REGARDING THE ACCESS AND PROTECTION OF HEALTH INFORMATION**
- **THE GENERAL PUBLIC MUST BE EDUCATED ABOUT SURETY ISSUES ASSOCIATED WITH ELECTRONIC HEALTH INFORMATION AS WELL AS THE GENERAL CAPABILITY OF TECHNOLOGIES TO ADDRESS THESE ISSUES**

CRITICAL INFRASTRUCTURE AND CORE COMPETENCIES

The following table summarizes the list of key technology and policy drivers and the infrastructure and core competency areas to which they relate.

KEY DRIVERS	INFRASTRUCUTRE AND CORE COMPETENCIES
A nationally accepted prioritized set of surety requirements for electronic health information will be defined, driving the information technology industry to develop products to enable the vision.	A consortium of the users of electronic health information systems should be formed to develop these requirements and drive policy formation. Although technologists should be consulted by this consortium, care must be taken to prevent this from becoming a marketing forum.
A strong partnership between surety technology and legal entities must be formed in order to produce effective legislation regarding the access and protection of health information.	A long term alliance between surety technologists, policy makers and legislators must be formed.
The general public will be knowledgeable about surety issues associated with electronic health information.	A commission should be formed within the US Department of Health and Human Services to educate the general public concerning electronic health information surety issues.

A nationally accepted, prioritized set of surety requirements for electronic health information is critical for the efficient and effective deployment of sure health and health care information systems. While surety products are being developed and used by the health care community, the envisioned benefits cannot be fully realized until the products are interoperable. Experience has demonstrated that the mechanisms for information surety are very intolerant to incremental changes.

A consortium representing the wide range of health information system users should be formed to address the interoperability of surety technologies. From the past experiences of similar efforts, it is suggested that membership in this group be limited to users to prevent the use of this consortium as a forum for the marketing of information technologies. The consortium should access technologists, universities and other research institutions, as well as vendors, for consultation on the state of the technologies available for solutions. Once the user community defines the needs and requirements, implementation within the bounds of standards may then be left up to the vendors. Leaving the

Fully interoperable surety products are required for health care information systems

implementation to the vendor allows for competition and better products, while the actual requirements developed by the consortium assures that products will be created to meet all users' needs and still optimize time to market.

Close interaction of technologists and policy makers will ensure that policies remain current

An information exchange forum must be organized to keep technologists and policy makers in step with the rapid change of technology. Within the forum, technologists may inform policy makers of upcoming technologies, techniques, products, and standards to improve the surety of health and healthcare information. Likewise, policy makers may inform technologists of surety technology capabilities to assure reasonable enforcement of surety requirements. By this forum or similar mechanism, the nation's legal statutes may remain current with available technologies.

Citizens should be made aware of the benefits of health and health care information technologies

The average citizen should be educated with the technologies and procedures used to provide surety in health information systems, just as the citizen needs to be educated with other technologies used to provide better health care. Much of the current public dialogue concerning surety consists of either scare tactics or technology hype. This education process might emphasize literature and publicly presented information addressing the proper handling of health information. A commission within the Department of Health and Human Services might be an appropriate choice to serve this function since the Department is generally responsible for informing the public in many areas of health concerns. In addition, a commission at this level might also support the development and distribution of high level health information system requirements.

OPPORTUNITIES AND SHOWSTOPPERS

There are many opportunities for information surety technologies to provide solutions to problems in the health information area. While these technologies contribute important solutions, the health and health care community has the opportunity to drive the direction of technology, or at least product development, with a clearly articulated vision.

As many have pointed out, the community has not been successful in reaching consensus on global health and health care information issues. The fundamental challenge will be to define a cross agency team to gain consensus in addressing the health and health care issues.

A second challenge will be getting policy makers and technologists to work together to craft effective legislation governing health and health care information. This legislation must not stifle surety technology development nor overburden health care providers. In addition, the legislation should allow strengthened surety requirements as new technologies are made available.

The health care community has the opportunity to influence technology

Consensus is required

Policy makers and technologists must work together to develop effective legislation

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AHIMA	American Health Information Management Association
API	Application Interface
ASTM	American Society for Testing of Materials
ATM	Asynchronous Transfer Mode
EDI	Electronic Data Interchange
HDROM	High Density Read Only Memory
HiPPI	High Performance Parallel Interface
HL7	Health Language 7
HPCC	High Performance Computing Consortium
I/O	Input/Output
ISDN	Integrated Services Digital Network
JCAHO	Joint Commission on Accreditation of Health Care Organizations
NCQA	National Committee on Quality Assurance
OC	Optical Carrier (i.e. OC-3: 155Mb/s, OC-12: 622Mb/s)
OO	Object Oriented
OTA	Congressional Office of Technology Assessment
PKI	Public Key Infrastructure
RAID	Redundant Array of Independent Disks
RAM	Random Access Memory
SCSI	Small Computer Systems Interface
Sonet	Synchronous Optical Network

Access Controls: Mechanisms for limiting and controlling access to data in an information system.

Authentication: Verification that data or a user is genuine.

Availability: The ability to use or access data and system resources as required.

Biometrics: Unique characteristics of a human being that can be measured to identify a particular person, e.g. fingerprints, hand geometry, retinal prints.

Confidentiality: The protection of information from unauthorized viewing.

Cryptology: The science of secret writing.

Data Mining: Extracting appropriate and comprehensible information from large volumes of unstructured data. There is a significant effort to use intelligent agents to support this task.

Digital Signature: The digital equivalent of a personal signature, calculated as a function of the data being signed, date and time of the signature, and a secret owned exclusively by the signer.

Encryption: The scrambling of information into an unrecognizable form which, with the knowledge of the right key, can later be retrieved.

Firewall: A generic name for a device that provides protection from entry and/or exit across network domains.

Information Security: A term used to include protection attributes such as privacy, integrity, and availability.

Information Surety: The balancing of system protection attributes such as privacy, integrity, and availability.

Integrity: The correctness and appropriateness of the content of a piece of information.

Intelligent Agent: A software entity authorized to act on another's behalf, which embodies the following notions:

Autonomous: The agent has initiative. It exercises control over its own actions.

Goal-Oriented and Flexible: The agent accepts high-level requests indicating what its user wants, but the agent is responsible for the details of satisfying those requests.

Interactive: The agent can ask its user for clarification of the high-level requests.

Adaptive: The agent's actions change depending on its user's changing preferences and the agent's changing environment.

Self-Starting: The agent can act based on environmental changes, in addition to direct invocations by its user.

Temporal Continuity: The agent is a continuously running process.

Mobile and Communicative: The agent can move from one machine to another – ideally across architectures and platforms. The agent can interact autonomously with other agents.

Network Surety: The balancing of privacy, integrity, and availability of information while traversing a network.

Object: A software component which is an identifiable, encapsulated entity that provides one or more services.

Privacy: Used by information surety technologists interchangeably with Confidentiality.

Secure Object: An object that incorporates security features.

Surety: The property of being correct, timely, safe and secure.

Timestamping: The process of associating a date with digital information.

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appendix a

AMERICAN HEALTH INFORMATION MANAGEMENT ASSOCIATION (AHIMA)

A professional organization for health information management professionals. According to its World Wide Web page (<http://www.ahima.org/cgi-bin/imagemap/mission.homepage?1164,40>), AHIMA is committed to the quality of health information for the benefit of patients, providers, and other users of clinical data. AHIMA provides leadership in Health Information Management (HIM) education and professional development; sets and promotes professional practice standards; advocates patient privacy rights and confidentiality of health information; influences public and private policies, including educating the publicly regarding health information; and advances health information technologies.

AMERICAN SOCIETY FOR TESTING OF MATERIALS (ASTM) E31

Committee on healthcare Informatics. Its mission is to develop standards for classifications, guides, specifications, practices, and terminology for the architecture, content, storage and communication of information used in healthcare. These standards also address data integrity and privacy issues.

CONGRESSIONAL OFFICE OF TECHNOLOGY ASSESSMENT (OTA)

Established by Congress in 1972 and closed on September 1995. According to archived OTA World Wide Web site (<http://www.ota.nap.edu>), OTA provided congressional committees with analyses of emerging, difficult, and often highly technical issues. Services included major assessment reports, background papers, briefings, and testimony. OTA explored complex issues involving science and technology, helped Congress identify policy options, and provided foresight about new development that could have important implications for future federal policy.

INSTITUTE OF MEDICINE

A component of the National Academy of Sciences. As stated on its home page (<http://www2.nas.edu/iom/2122.html>), its mission is to advance the scientific knowledge and the health and well-being of all people of this nation and the world consistent with the role conferred by its congressional authority.

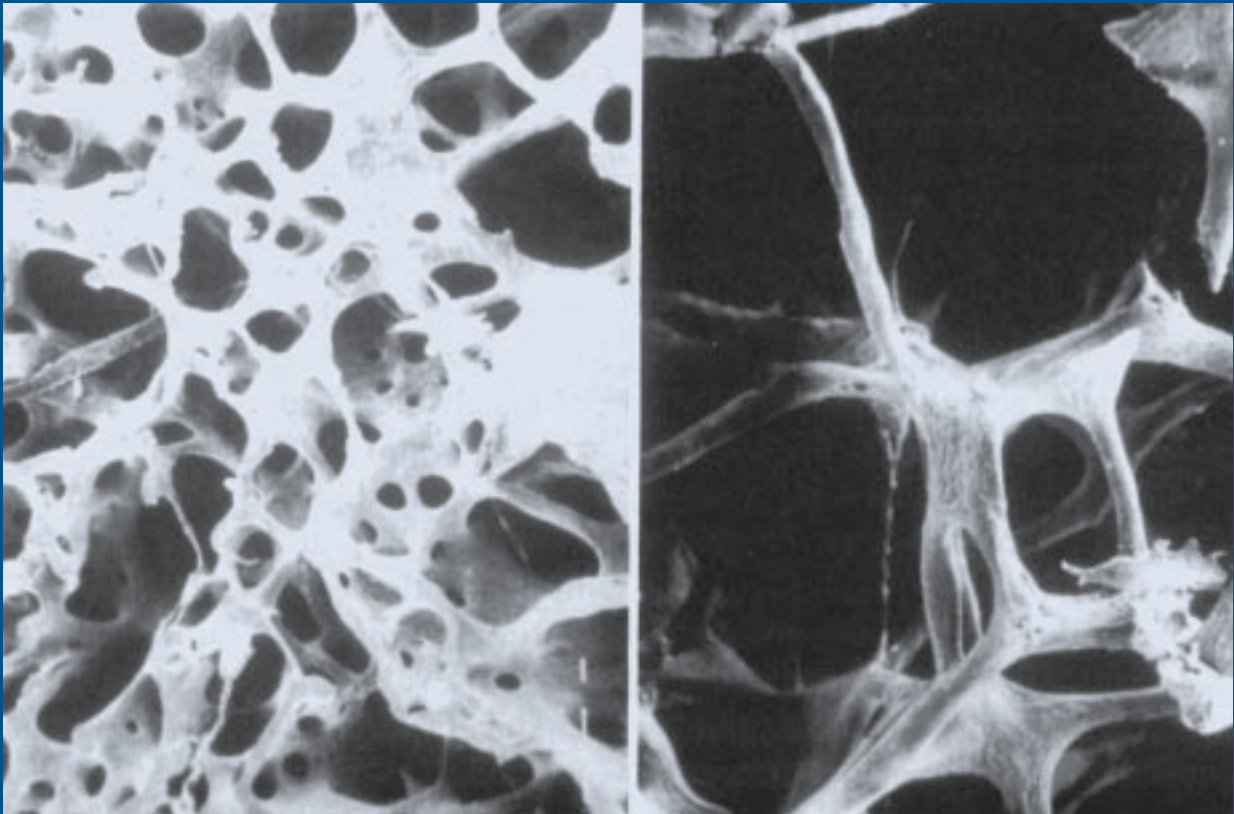
INTEGRATED PREDICTIVE DIAGNOSTICS TECHNOLOGY ROADMAP

MODEL-BASED HEALTH MONITORING AND PREDICTION TO ENABLE TAILORED INTERVENTIONS FOR IMPROVED OUTCOMES

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This Roadmap addresses the association of diagnostic measurements with models of a disease process to predict the most likely evolution of a disease in a particular patient and thereby provide an improved basis for tailoring the care intervention. This combined sensor-model approach, to both assess current conditions and predict future changes in configuration, is applicable to a broad range of maladies. The two conditions described in this Roadmap, osteoporosis and sudden cardiac death, represent extremes in the rate of disease development. Current research suggests that these two conditions are excellent candidates to be addressed by the combined sensor-model approach.

(Photography by Dr. Jan Kosek)



DESCRIPTION

Diagnostic technologies that predict serious health conditions can reduce cost and improve health care

Some modern medical procedures have been developed as analogs of methods employed in evaluating machinery health. In both disciplines (medical and machinery), the capability to detect precursors to serious conditions and to predict the time for a condition to reach a critical stage has an enormous potential payoff, especially in terms of tailoring intervention strategies.

Goal: This Integrative Predictive Diagnostics Technology Roadmap addresses the development of technologies that will provide predictive indications of the onset of serious health conditions. Such diagnostics technologies have the potential to simultaneously reduce the cost and improve the quality of health care.

The following examples illustrate the dual utilization of technologies in both medical and machinery applications:

- **Bore Scope:** The bore scope is a fiber-optic bundle permitting examination of the interiors of complex machines (e.g., turbine) with no or minimal disassembly. The success of the bore scope was one of the inspirations for the development of optical fiber-based, orthoscopic tools for minimally invasive medical diagnostics and treatments.
- **Usage Monitoring Systems:** Health and Usage Monitoring Systems (HUMS) are employed on complex machinery (e.g., helicopters) to monitor equipment status and predict time to failure. For example, subtle changes in the vibration signature of a helicopter gearbox, monitored by externally mounted accelerometers, precedes gearbox failure by tens of hours.
- **Industrial Monitoring Systems:** Industrial manufacturing plants are frequently monitored by multi-sensor systems to detect anomalous operating conditions and to ensure continued quality of the manufacturing process.

These developments in the machinery domain naturally lead to a fundamental question:

Are there medically important conditions where both the precursors to a critical condition can be identified and accurate prediction methods developed for the time required to reach this critical stage?

This represents a formidable challenge, involving both improved diagnostic methodologies and models of physiological systems and associated disease processes. The capability to detect

precursors to serious conditions and to predict the time for a condition to reach a critical stage has an enormous potential payoff, especially in terms of tailoring intervention strategies. Therefore, this area is proposed as an active area of health care technology research and development.

The technical challenges associated with developing such a predictive diagnostic capability is well illustrated by two important and representative conditions: osteoporosis and sudden cardiac death.

- **Osteoporosis** is a progressive condition that involves a very gradual reduction in bone mineral density and deterioration in the micro architectural characteristics of bone tissue
- **Sudden cardiac death**, on the other hand, often occurs without apparent warning to the patient or even to an examining physician who has seen the patient a few days earlier
- Examples of other conditions with a gradual progression include glaucoma, a range of cancer types, and restenosis following medical procedures such as angioplasty
- More sudden events include seizures and a variety of complications that can occur when a patient is under general anesthesia

By resolving the issues associated with predictive diagnostics for osteoporosis and cardiac electrical instability, relevant information for the development of a similar capability for other disease processes may be learned as well.

TECHNOLOGY AND POLICY OBJECTIVES

The objectives over the next 15 years are as follows:

1. **EXTEND THE OF PREDICTIVE DIAGNOSTICS METHODOLOGY TO ADDRESS CRITICAL MEDICAL CONDITIONS WITH IMPROVED DIAGNOSTICS, PROGNOSTICS, AND INTERVENTION STRATEGIES**
2. **SIGNIFICANTLY REDUCE MORBIDITY AND MORTALITY ASSOCIATED WITH OSTEOPOROSIS THROUGH EARLIER DIAGNOSIS AND TAILORED INTERVENTIONS TO ACHIEVE IMPROVED OUTCOMES**
3. **REDUCE SUDDEN CARDIAC DEATHS BY ADVANCED DIAGNOSTICS AND PREDICTIVE TOOLS USED IN PHYSICIANS' OFFICES AND IN THE HOMES OF HIGH-RISK PATIENTS**
4. **HELP PHYSICIANS IDENTIFY THE POTENTIAL FOR RESTENOSIS THROUGH IMPROVED SENSING, DIAGNOSTICS, AND PREDICTION OF POST-PROCEDURE BEHAVIOR**
5. **SIGNIFICANTLY IMPROVE THE EARLY DETECTION AND TRACKING OF SELECTED CANCERS TO HELP PHYSICIANS SELECT APPROPRIATE INTERVENTION STRATEGIES**

TECHNOLOGY AND POLICY ROADMAPS

A list of the requirements and drivers necessary to meet the objectives in the near (0 to 3 years), intermediate (3 to 6 years) and far (6 to 15 years) terms are defined by the Roadmaps that follow.

OBJECTIVE 1: EXTEND THE PREDICTIVE DIAGNOSTICS METHODOLOGY TO ADDRESS CRITICAL MEDICAL CONDITIONS WITH IMPROVED DIAGNOSTICS, PROGNOSTICS, AND INTERVENTION STRATEGIES

The Objective 1 Table provides a general Roadmap for developing predictive diagnostics for complex disease processes such as osteoporosis and sudden cardiac death. The specific steps will be different for each disease. For example, the type of improvements to current diagnostic systems will differ greatly for osteoporosis and sudden cardiac death. Moreover, the relative maturity of diagnostic and modeling capabilities differ radically for different medical conditions.

The following discussion provides additional details concerning osteoporosis and sudden cardiac death. Specific technology Roadmaps are provided for osteoporosis and for sudden cardiac arrest. Lessons learned in developing these two conditions will facilitate subsequent implementation of predictive diagnostics for restenosis, selected cancer types, and other conditions.

Improve diagnostics, prognostics, and intervention strategies

OBJECTIVE 1: Extend the predictive diagnostics methodology to address critical medical conditions with improved diagnostics, prognostics, and intervention strategies

Technical Attributes	Units or Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Improved diagnostics (more precise identification of health state)	Percent probability of correct diagnosis False alarm rate Lead time for detection	Numerous sensing systems Physician interpretation of results Not model-based	Full state space treatment of data to identify key observables Investigate non-invasive observables (e.g., active and passive acoustics and wideband DSP) Develop physicians' assistant for data visualization and interpretation Establish framework for multi-sensor data fusion	Application of nonlinear models for characterization Critical evaluation of existing sensing technologies Approximate reasoning for intelligent diagnostic support Develop approach for high-risk patient monitoring	Deploy and use non-invasive multi-sensors in physician offices and hospitals Clinical trials of portable monitoring system for high-risk patients
Develop predictive capability (predict the time evolution of the health state)	Prediction accuracy as a function of prediction time horizon	Very limited to no model-based prediction	Feasibility study of predictive modeling on existing data sets Database of measurements for at risk, normal populations Requirements for improved sensing Architecture and reasoning approach for data fusion and model interpretation	Nonlinear models for prediction Requirements and system architectures for turnkey systems	Noninvasive monitoring of high-risk patients Accurate prediction to allow tailored interventions
Improved intervention strategy	Recovery time Increased mobility Reduced number of broken bones	N/A	Develop just-in-time intervention strategy	Clinical test integrating improved diagnostics into intervention strategy	Clinical tests integrating model-based prediction into intervention strategy

OBJECTIVE 2: SIGNIFICANTLY REDUCE MORBIDITY AND MORTALITY ASSOCIATED WITH OSTEOPOROSIS THROUGH EARLIER DIAGNOSIS AND TAILORED INTERVENTIONS TO ACHIEVE IMPROVED OUTCOMES

In the United States, there are more than 500,000 vertebral and 250,000 hip fractures each year. The vast majority of these injuries are sustained by older adults. Hip fractures alone are fatal in 12% to 20% of this population, and fully half of those who survive require long-term nursing care with an estimated annual cost in the \$10B range. Given current demographic trends, these age-related fractures have the potential for becoming dominant health care cost and quality of life issues in the future.

A primary cause of age-related fractures is osteoporosis, a loss in bone mass and deterioration in the micro-architectural characteristics of bone tissue. The attendant reductions in skeletal strength are sufficient to cause bone fracture from a fall from the standing position or from even more common activities such as lifting. While both men and women lose bone mass as part of the normal aging process, the loss is accelerated in women shortly before and at the onset of menopause. Among the earliest observable signs of vertebral osteoporosis may be a decrease in height. At more advanced stages, a disfiguring dowager's hump may appear, not because of poor posture but rather a permanent anterior wedging resulting from osteoporotic fractures of the thoracic vertebrae. These external signs of vertebral osteoporosis are sometimes, but not always, observed in patients skeletal fragility in other locations (e.g., the hip, wrist, and even the chest cage or ribs).

Although osteoporosis is most commonly associated with low estrogen levels and the attendant increased resorption of bone, other factors can contribute as well. For example, some illnesses can cause bone loss (e.g., hyperthyroidism) as can the long-term use of some medications (e.g., immunosuppressants), excess alcohol or smoking.

The most common methodology for clinical assessment of osteoporosis is a bone densitometry measurement. Variants of this measurement include single and dual photon absorptiometry and, most recently, dual-energy x-ray absorptiometry. Since osteoporosis is also dependent on bone strength, such measurements appear to have only a partial ability to distinguish between patients who will or will not experience fracture. Some studies have shown statistically significant separations in densitometric measures at the hip and spine between fracture patients and control groups.

Other studies involving elderly populations (mean age of 87) of statistically significant size show no significant difference in bone density in females who experienced a fracture compared with those who did not experience a fracture (for a given type of fall). In contrast, in this same study, bone mineral

Develop earlier diagnosis of osteoporosis and improve outcomes

Osteoporosis is a primary cause of age-related bone fracture

Bone densitometry does not alone predict which patients will experience bone fracture

Bone density in females does not predict fracture for a given fall

OBJECTIVE 2: Significantly reduce morbidity and mortality associated with osteoporosis through earlier diagnosis and tailored interventions to acheive improved outcomes

Technical Attributes	Units or Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Improved diagnostics (more precise identification of health state)	Percent probability of correct diagnosis False alarm rate Lead time for detection Improved ability to distinguish between patients who will or will not experience bone strength failures	Bone densitometry measurements Single and dual photon absorptiometry Dual energy x-ray absorptiometry Physician interpretation of results	Full state space treatment of data to identify key observables Investigate noninvasive observables (e.g., active acoustics and wideband DSP) Develop physicians' assistant for data visualization and interpretation Establish framework for multi-sensor data fusion	Application of non-linear models for characterization Critical evaluation of existing sensing technologies Approximate reasoning for intelligent diagnostic support Ability to noninvasively sense bone micro-architecture	Deploy and use noninvasive multi-sensors in physician offices and hospitals
Develop predictive capability (predict the time evolution of the health state)	Prediction accuracy as a function of prediction time horizon	Limited to predictions of susceptibility based on statistical predispositions	Feasibility study of predictive modeling on existing data sets Database of measurements for at risk, normal populations Requirements for improved sensing Architecture and reasoning approach for data fusion and model interpretation	Nonlinear models for prediction Requirements and system architectures for turnkey systems Structural models for bone strength allowing prediction of effects of falls, etc.	Noninvasive monitoring of high-risk patients Accurate prediction to allow tailored interventions, e.g., based on cyclically loaded fatigue/damage analog to mechanical systems
Improved intervention strategy	Recovery time Increased mobility Reduced number of broken bones	N/A	Develop hybrid intervention strategy involving prevention, life style changes, etc.	Clinical tests integrating improved diagnostics into intervention strategy	Clinical tests integrating model-based prediction into intervention strategy

density was found to be a predictor of hip fracture in men. One explanation for this dichotomy is that the majority of women in their middle 80s have sufficiently reduced bone density to cause a fracture in a fall which is not true for men. This contention is supported by biomechanics studies in which the stress imposed by a fall is compared with estimated bone strength. Additionally, some studies have shown that bone densitometry measurements do correlate with the likelihood of fracture during a fall for younger women (i.e., nominal age 70 and below).

In considering the diagnostic and modeling challenges and opportunities relevant to osteoporosis, it may be helpful to note the many parallels between the skeletal system and a structure made of more readily characterized engineering materials. Some are as follows:

• SPATIAL DISTRIBUTION OF APPLIED LOAD

The likelihood of failure depends on the spatial distribution of the applied load, with localized load application more problematic than distributed load application. In a fall, older adults are much more likely to fall sideways (and strike the hip joint where there is little protection from the muscle and fatty tissue present in middle-aged people).

• ELEMENT GEOMETRY

The geometry of individual elements is important. Orientals have about one half the hip fracture rate of Caucasians because of the relative length and angle of the femoral neck segment (e.g., the hip axis length).

• MICROARCHITECTURE

The microarchitecture of the bone is of critical importance as is the microstructure of an engineering material. The architecture of cancellous bone exhibits an array of trabecular elements parallel to the principal axis of force and another orthogonal to it. In vertebral osteoporosis, electron micrographs show a preferential loss of the bracing trabeculae occurs which leaves long, unsupported load-bearing elements. By the same token, apparently identical metal alloys can have differing strength if they have been heat treated differently because of the resultant differences in microstructure. Two composite materials will have very different strength if the length and orientation of the reinforcing fibers differ.

Bone density predicts occurrence of hip fracture in males

Multiple skeletal structural characteristics should be considered for a diagnosis

• **FATIGUE DAMAGE**

Fatigue damage occurs in bone as in any cyclically loaded engineering material. One of the functions of osteocycles in bone is to detect excess strains and initiate the process which resorbs damaged bone and replaces it with defect-free bone. A range of conditions can cause this process to be sluggish or to fail entirely leading to an accumulation of micro damage to the point of structural failure. A similar accumulation of micro damage in engineering materials, resulting in fatigue crack growth, is perhaps the single most important failure mode in common structures. It is a principal source of difficulty with aging aircraft and individual structural elements such as gears, bearings, shafts and bridge struts.

Predictive diagnostics used for mechanical systems can be leveraged for osteoporotic bone care

Noninvasive monitoring and physical modeling of effects such as microstructural changes, and crack initiation and growth are a major focus of current research on predictive diagnostics of mechanical systems. In the near term, the potential utility of adaptations of these methods to osteoporotic bone needs to be examined. Similarly, current work on ultrasonic methods of analyzing the skeletal structure may suggest new approaches for mechanical systems. The potential for synergism appears high. In the longer term, fundamentally new sensing, signal processing, and modeling methods may be required for a true predictive capability for osteoporosis and for mechanical systems.

Improved methods of early measuring and modeling of bone conditions are needed for later prediction of fracture occurrence

Early attention is also needed to improve methods of measuring and modeling bone condition. The adequacy of existing databases for projecting the temporal change in bone structure should be examined. In later stages, these efforts could be merged with biomechanical models of load distribution in selected types of falls. This would provide the basis for predicting the likelihood of fracture at the time measurements are made and would extend this prediction into the future based on realistic assumptions and databases describing the change in bone structure with time. Only on the basis of solid predictive data can effective prophylactic or preventive measures be formulated, thereby leading to reduced medical costs.

OBJECTIVE 3: REDUCE SUDDEN CARDIAC DEATHS BY ADVANCED DIAGNOSTIC AND PREDICTIVE TOOLS USED IN PHYSICIANS’ OFFICES AND IN THE HOMES OF HIGH-RISK PATIENTS

Sudden cardiac death is a major contributor to premature mortality in the United States. It is the leading cause of death in men ages 20-60 and, in the aggregate, accounts for approximately 500,000 fatalities per year. The main, immediate cause of sudden cardiac death is known to be ventricular fibrillation, an abnormally rapid cardiac rhythm. Historically, the healthy heart has been presumed to

Develop advanced tools to diagnose and predict heart failure

OBJECTIVE 3: Reduce sudden cardiac deaths by advanced diagnostics and predictive tools used in physicians’ offices and in the homes of high-risk patients

Technical Attributes	Units or Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Improved diagnostics (more precise identification of health state)	Percent probability of correct diagnosis False alarm rate Lead time for detection	EEG recordings, etc. Physician interpretation of results Not modeled based	Application of time-frequency domain and recurrent neural networks for EEG signal characterization Investigate non-invasive observables Establish framework for multi-sensor data fusion	Application of non-linear models for characterization Critical evaluation of existing sensing technologies Approximate reasoning for intelligent diagnostic support Develop approach for high-risk patient monitoring, e.g., wrist watch size monitors	Deploy and use non-invasive multi-sensors in physician offices and hospitals Clinical trials of portable monitoring system for high-risk patients Extend localized cardiovascular system models to include the autonomic control system and the respiratory system
Dvelop predictive capability (predict the time evolution of the health state)	Prediction accuracy as a function of prediction time horizon	No model-based prediction Identification of “at-risk” patients based on lifestyle and medical history statistics	Feasibility study of predictive modeling on existing data sets Database of measurements for at risk, normal populations Requirements for improved sensing Architecture and reasoning approach for data fusion and model interpretation	Nonlinear models for prediction Requirements and system architectures for turnkey systems Evaluate models such as correlated stochastic processes, nonlinear deterministic systems, and hybrid systems	Noninvasive monitoring of high-risk patients Accurate prediction to allow tailored interventions
Improved intervention strategy	Mortality rate Recovery time	N/A	Develop just-in-time intervention strategy	Clinical tests integrating improved diagnostics into intervention strategy	Clinical tests integrating model-based prediction into intervention strategy

beat with great regularity and abnormal conditions such as ventricular fibrillation to be characterized by a chaotic-like irregularity. However, during the past decade, studies of heart rate variability in both animals and humans have suggested that the opposite appears to be true. The healthy heart beat shows a complex, fractal type variability, whereas the electrical activity of the heart immediately prior to, or even during, sudden cardiac death are often surprisingly regular. The mechanism of fibrillation itself remains elusive, but it is apparently not related to fractal or chaotic dynamics. These observations have a remarkable parallel to some complex mechanical systems where the behavior shows no discernible regularity until a dominant fault occurs which ultimately leads to failure.

An intriguing question is suggested by these observations:

Is a breakdown in the normal fractal pattern of heart rate variability in ambulatory electrocardiogram (ECG) recordings a reliable precursor to ventricular fibrillation or other serious heart conditions?

An affirmative answer could potentially alleviate the need for more costly and risky invasive procedures for many patients and provide the advance warning necessary to tailor interventions to avoid or minimize the damage caused by the event. In recent years a range of studies conducted by premier medical schools and hospitals in the United States has focused on this question. The reported findings to date are not completely consistent, but they generally support the following conclusions:

**Decreased heart rate variability
is a good predictor**

- Decreased heart rate variability is a good, long-term predictor of overall and arrhythmic death after a myocardial infarction
- The simplest measure of heart rate variability, the standard deviation, uncovers no consistent trend as the time of onset of ventricular fibrillation is approached
- More sophisticated measures of the degree of heart rate variability or complexity have been developed which are more likely to have this capability. Two that have been identified in the cardiology literature are Approximate Entropy (ApEn) and Detrended Fluctuation Analysis (DFA). Both measures are designed to measure complexity or irregularity but not to distinguish underlying model form. Other potentially useful measures include common frequency domain methods (power spectrum or higher order spectrum) and wavelet transform methods

**Mathematical models are
being considered to study
heart rate variability**

Recently, significant attention has been given to the development of mathematical models for heart rate variability. A few, relatively simple parameter models have been shown to adequately represent the contrast between the healthy heart and extreme pathological conditions such as congestive heart failure. It has become clear, however, that much more complex models are required to adequately

represent the smaller changes in heart rate variability of greatest interest for predictive diagnostic purposes. Models under active consideration range from correlated stochastic processes to mixtures of such processes and nonlinear deterministic systems. Ideally, such a model would provide a mechanistic explanation of the heart rate spectrum characteristic of healthy subjects and the more periodic dynamics associated with precursors to sudden cardiac death. It is expected that such a model must account not only for intrinsic characteristics of the cardiovascular system but also its interaction with the autonomic control system and the respiratory system.

The primary early requirements are improved precursor detection capabilities and improved cardiovascular system, autonomic control system representations. The most promising detection and modeling methodologies then need to be combined to provide a predictive capability. The work already in progress for machinery predictive diagnostics provides tools that should be applied in the current context for automated recognition of ventricular fibrillation precursors, and for establishing the ultimate limits of predictability of a life-threatening cardiac event.

**The most promising models
would include prediction of a
life-threatening cardiac event**

TECHNOLOGY AND POLICY DRIVERS

The principal technology drivers associated with the success of the above objectives are summarized below.

• IMPROVE DIAGNOSTICS

The use of new sensors, improved signal processing for existing sensors, multi-sensor data fusion, and automated approximate reasoning will improve the capability to characterize the human biological system (viz. to diagnose the health or status of a human).

• DEVELOP PREDICTIVE CAPABILITY FOR THE EVOLUTION OF THE DISEASE PROCESS

The development of predictive models, which provide an estimate of the evolution of the “trajectory” of a health (state) vector, will improve the representation of the condition for a human biological subsystem.

• IMPROVE INTERVENTION STRATEGIES BASED ON THE FUSION OF DIAGNOSTIC AND PREDICTIVE METHODOLOGIES

Improved detection and prediction of disease process (e.g., changes to life styles, new combined interventions, etc.) will advance new strategies for medical intervention.

CRITICAL INFRASTRUCTURE AND CORE COMPETENCIES

The following table summarizes the key infrastructure elements and potential funding sources associated with the development of predictive diagnostics for improved health care delivery. Also included in this table are infrastructure elements indirectly related to predictive diagnostics for medicine. For example, developments in this arena may be extendible to other processes (e.g., improved monitoring and diagnosis of industrial processes).

Infrastructure Element	Benefits (1-5)	Primary Benefit	Agency	Project Contribution (1-5)	Primary Contribution	Agency
Individuals	5	Improved individual health with greater economy	VFW AARP Other foundations & advocacy groups	N/A	N/A	N/A
Defense (Noncombat)	5	Improved health of military families and dependence	VA Military	3	Improved sensors Improved DSP & data fusion Math techniques fro prediction via CBM funding Information processing	ONR DARPA Intelligence agencies
Defense (Combat)	2	Improved diagnosis & treatment on the battlefield	Military	3	Improved sensors Improved DSP & data fusion Math techniques fro prediction via CBM funding Information processing	ONR DARPA Intelligence agencies
Manufacturing and Industry Consumers of IPD	4	Improved monitoring of industrial processes, CBM, etc.	Various companies	4	Improved sensors Failure prediction techniques	Various companies
Deficit	4	Reduced health costs	OMB	N/A	N/A	N/A

The table lists key infrastructure elements and identifies the anticipated magnitude of the benefits (on a scale from 1 to 5), a summary of the primary benefits, identification of potential funding agencies, project contributions, and associated contributions and agencies for each element. Note that significant benefits of the recommended research would be realized by individuals through improved health. Secondary benefits would be realized by reduced national deficit and technology transfer to manufacturing and industrial consumers. Infrastructure elements include:

- Individuals whose health would benefit from improved care
- Individuals and organizations within the defense community
- Manufacturers and industrial organizations which could benefit from improved capability to monitor industrial processes
- The national deficit would be reduced by improved health care at reduced cost
- The combat elements of the defense community would benefit with improved diagnosis of battlefield injuries

OPPORTUNITIES AND SHOWSTOPPERS

The development of predictive diagnostics for medical conditions leverages a highly relevant research and development base for machinery diagnostics and prognostics. Key opportunities and potential showstoppers are listed below.

Machinery diagnostics and prognostics can be leveraged for medical conditions

- **RAPID EVOLUTION OF NEW SENSORS, ADVANCED MICROPROCESSORS, NEW SIGNAL PROCESSING TECHNIQUES AND MULTISENSOR DATA FUSION TECHNIQUES, FUNDED BY DEPARTMENT OF DEFENSE (DOD) RESEARCH, PROVIDE A TREMENDOUS OPPORTUNITY FOR APPLICATION TO MEDICINE**

Properly applied, these could demonstrate immediate benefits for improved diagnostics of medical conditions, especially improved diagnostics for osteoporosis and improved prediction for sudden cardiac death.

- **IMPROVED PREDICTION MODELS REQUIRE SYSTEMATIC COLLECTION AND ANALYSIS OF EXTENSIVE AMOUNTS OF RELEVANT DATA**

These data must be collected, filtered, and analyzed without regard to preestablished agendas. A data collection and test plan must be developed.

- **DIAGNOSIS AND PREDICTION TECHNIQUES ARE AT RISK FOR DRAWING LIABILITY LAWSUITS**

Health policies must be established to encourage the introduction of these technologies without fear of undue liability on the part of health care providers or manufacturers, etc.

- **EFFECTIVE TECHNOLOGY TRANSFER FROM DOD RESEARCH (E.G., IN DIGITAL SIGNAL PROCESSING, MULTISENSOR FUSION, ETC.) WILL REQUIRE BREAKING DOWN HISTORIC COMMUNICATIONS BARRIERS BETWEEN THE MEDICAL COMMUNITY AND THE DOD RESEARCH COMMUNITY**

Joint conferences, multidisciplinary university research initiatives, and other forums should be developed to encourage this communication.

AARP	American Association of Retired Persons
ApEn	Approximate Entropy
CBM	Condition Based Maintenance
DARPA	Defense Advanced Research Projects Agency
DFA	Detrended Fluctuation Analysis
DoD	Department of Defense
DSP	Digital Signal Processing
ECG	Electrocardiogram
EEG	Electroencephalogram
HUMS	Health and Usage Monitoring Systems
OMB	Office of Management and Budget
ONR	Office of Naval Research
VA	Veterans Administration
VFW	Veterans of Foreign Wars

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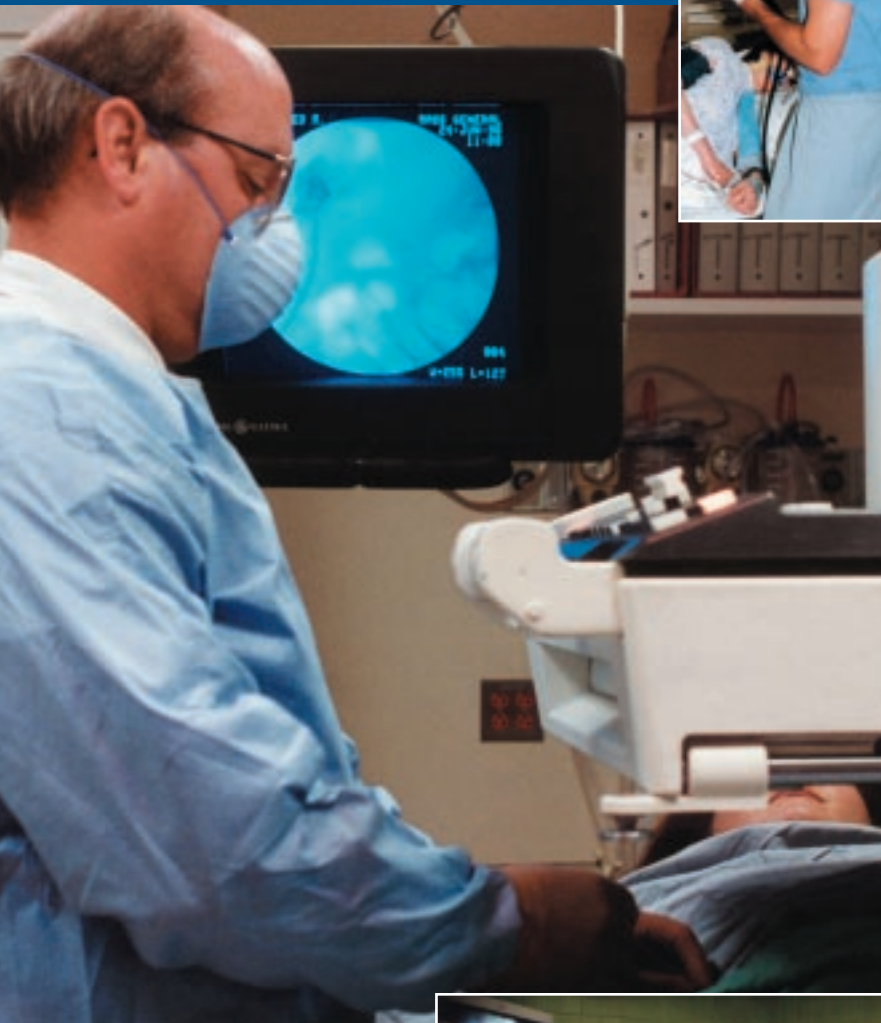
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MINIMALLY INVASIVE THERAPIES, IMAGING, AND ENERGY DELIVERY SYSTEMS TECHNOLOGY ROADMAP



The integration of minimal access surgery, cross-sectional imaging and fiber-optic endoscopy has brought a new era of medical care. Many surgical procedures once performed through large, painful incisions, can now be accomplished through percutaneous access routes with digital image guidance. In some cases, surgical procedures can be completely replaced by endoscopic or catheter-based endoluminal therapies. This revolution in care has meant shorter recovery times for patients and faster return to daily activities. The tide of change to progressively less invasive therapies will continue as newer procedures are developed, driven by patient demand for minimal disfiguration and disability as well as employers' desire to minimize disability

costs. This Roadmap outlines the most likely directions of fruitful development in medical technology applied to minimally invasive therapies, imaging and energy delivery.



DESCRIPTION

MIT reduces trauma and recovery time

Minimally Invasive Therapy (MIT) can be defined as those procedures which deliver treatment using less invasive and less traumatic methods than were previously available. Common examples are the advent of laparoscopic methods of gallbladder and fallopian tube surgery, endoscopic treatment of diseases of the gastrointestinal tract, and percutaneous catheter-based procedures such as angioplasty. The goal of each of these types of procedures is to replace a treatment which causes difficult or dangerous recovery with an equally effective procedure which has faster recovery and less morbidity. This Roadmap outlines the opinions of a panel of 26 expert physicians and medical researchers in the fields of minimally invasive therapy, imaging, and energy delivery. These experts considered the areas for technology development which could have the greatest impact on patient care in the next 15 years.

The common goal is to provide the most rapid return to well being possible following an effective therapeutic intervention.

The impact of minimally invasive techniques on the overall health of our society is undeniable. As an example, in the past decade, surgical treatment of nephrolithiasis (kidney stones) has been irreversibly changed by extracorporeal shock-wave lithotripsy (ESWL). A previously common surgical procedure which carried a 1% mortality rate and a 4-6 week disability period has been replaced with an outpatient procedure in which death is virtually unheard of and disability is 1-2 days.

Synergistic techniques for MIT can be developed to address access, imaging and delivery

Most MITs include three basic components: access for tissue manipulation, imaging, and therapy delivery. This chapter describes a pathway for the introduction of novel techniques based on the synergistic interaction of imaging, access, and energy delivery. It is unlikely that major advances in MIT will occur without this synergy.

TECHNOLOGY AND POLICY OBJECTIVES

The objectives over the next 15 years can be identified by two critical policy objectives and four technology objectives:

POLICY OBJECTIVES

1. TO ESTABLISH A SITE FOR SYNERGISTIC INTERDISCIPLINARY COMMUNICATIONS AND RESEARCH WHICH WILL SERVE AS A CENTER FOR TECHNOLOGY TRANSFER IN THE DEVELOPMENT OF NEW MINIMALLY INVASIVE THERAPIES
2. TO OPTIMIZE THE DELIVERY OF THERAPY AT THE APPROPRIATE POINT OF CARE

TECHNOLOGY OBJECTIVES

1. TO DEVELOP IMAGE-BASED METHODS OF TISSUE IDENTIFICATION AND CHARACTERIZATION AND MULTIMODAL IMAGE DISPLAY TECHNOLOGIES, WHICH WILL PROMOTE IMPROVED METHODS OF DETECTION OF DISEASE
2. TO ENHANCE AND EXPAND INNOVATIVE METHODS OF TISSUE RECONSTRUCTION AND ABLATION, PERMITTING REPAIR OR REMOVAL OF DISEASED TISSUE WITH THE LEAST TRAUMA TO THE PATIENT
3. TO DEVELOP METHODS TO ACCOMPLISH THERAPY USING THE LEAST INVASIVE ACCESS ROUTE FEASIBLE, ALLOWING RAPID RECOVERY AND RETURN TO FUNCTION
4. TO DEVELOP A SYSTEM FOR PROSPECTIVE EDUCATION AND ASSESSMENT DURING THE INTRODUCTION OF NEW TECHNOLOGIES AS A MEANS OF RAPIDLY DISSEMINATING NEW, EFFECTIVE MINIMALLY INVASIVE THERAPIES AND PREVENTING PREMATURE DISSEMINATION OF UNTESTED TREATMENTS

Some of the objectives (education and assessment, and optimal point of care) overlap with other areas of the complete set of Biotechnology Technology Roadmaps (i.e., Performance Measurement & Outcomes Research and Advanced Telemedicine), and additional information concerning those areas may be found in those Roadmap chapters.

TECHNOLOGY AND POLICY ROADMAPS

A list of the requirements and drivers necessary to meet the objectives in the near (0-3 years), intermediate (3-6 years), and far (6-15 years) term is presented in the tables which follow.

POLICY OBJECTIVE 1: ESTABLISH A SITE FOR SYNERGISTIC INTERDISCIPLINARY COMMUNICATIONS AND RESEARCH WHICH WILL SERVE AS A CENTER FOR TECHNOLOGY TRANSFER IN THE DEVELOPMENT OF NEW MINIMALLY INVASIVE THERAPIES

A Center for interdisciplinary research and development is essential

For the most effective use of research investments during the early, exponentially growing period of development of MITs, a centralized hub of interdisciplinary research and development is essential. When coupled with effective, concurrent outcomes analysis of novel techniques, this Center will serve as a “medical incubator” for new procedures.

POLICY OBJECTIVE 1: Establishment of a Center for MIT development

Policy attribute that drives success for the requirement	Currently Available	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Creation of a Center for MIT development	Isolated individual specialists, individual grants, and corporate programs	National Center of Excellence Interdisciplinary “medical incubator” Academic and corporate funding	Internet access to regional Centers of Excellence Fellowship training Early royalty stream aids funding	MIT subspecialty Shared environments of learning using VR technology Self-sustaining partnership funding with corporations

POLICY OBJECTIVE 2: OPTIMIZE DELIVERY OF THERAPY AT APPROPRIATE POINT OF CARE

To some extent, the delivery of therapy at the appropriate point of care is also considered in the Advanced Telemedicine Technology Roadmap. For the purposes of this Roadmap, the authors are particularly concerned that procedures and tools be designed with a goal of portability of therapy so that equivalent care can be given regardless of the location of that care. Although the current trend is for equal access to advanced procedures in every hospital location, we feel that further developments in minimally invasive therapies will favor a hub-and-spoke organization of care, with centers of excellence providing cutting edge, minimally invasive techniques and more common procedures being performed at the community, clinic, or office level. Tools designed for minimally invasive procedures will need to be compatible with the more intensive use of computers for imaging, target and tool tracking and smaller access ports which will accompany developments outlined elsewhere in this chapter. For further details, please refer to Appendix A.

Centers of excellence will advance cutting edge MIT technologies

Common procedures will be performed at community, clinic or office level

POLICY OBJECTIVE 2: Optimize delivery of therapy at appropriate point of care

Policy attribute that drives success for the object	Units of Metrics	Currently Available	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Portability of therapy	Equivalent care regardless of locus	Hospital based	Suburban therapy centers	Equal distribution in local and regional centers	Hub-and-spoke delivery: common procedures performed locally with regional, cutting edge “centers of excellence”
Telemedicine compatibility	Efficient, effective remote care	Teleradiology Teledermatology Teleconsultation	Network links to central facility In-house local telemedicine links between specialists	National access	Wideband, global access to multiple consultants Telesurgery
Tool design		Hospital O.R./procedure room-based	Speciality-based unique instruments	Cordless, self-powered, micromotors	Portable field access with digital transmission compatibility

TECHNOLOGY OBJECTIVE 1: DEVELOP IMAGE-BASED METHODS OF TISSUE IDENTIFICATION AND CHARACTERIZATION AND MULTIMODAL IMAGE DISPLAY TECHNOLOGIES WHICH WILL PROMOTE IMPROVED METHODS OF DETECTION OF DISEASE

Identification and localization of abnormal tissue is the key to MIT tool development

Minimally invasive therapy tools must assist the identification of abnormal tissue as well as the localization, the access, and the effective treatment of such tissue. The key to this sequence is the identification and localization of abnormal tissue. This Technology Objective 1 focuses on imaging methods which will enable advanced localized therapy. Many of the items listed in Table 1 require advanced computational applications to medical imaging. This should result from collaborations between academia, industry, and government to leverage investments currently being made in computing onto the field of clinical medical care, as opposed to genetic research and molecular pharmaceutical design where advanced computing is already firmly established. For further details, please refer to Appendix B.

TECHNOLOGY OBJECTIVE 1: Develop image-based methods of tissue identification and characterization, and multimodal image display technologies, which will allow improved methods of detection of disease

Technical attribute that drives success for the object	Units of Metrics	Currently Available	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Improved signal processing	Local blood flow Tissue texture	"Bright, dark" "Enhancing/ non-enhancing"	+/- increased perfusion	Ischemia mapping	Regional organ characterization
Image fusion	Function mapped to anatomy	Regional isotope activity in brain MR	Full mapping of brain function/anatomy	Organs outside CNS mapped	Functional CT and US mapping
"Molecular probes"	Tissue activity/identification	Increased or decreased blood flow	Blood pool agents for CT	US blood pool agents Tissue specific agents	Ligand-receptor agents specific for cellular type
Tissue Recognition/ Tissue "Transparency"	Edge detection and characterization	Detection determined by probe/pulse sequence	Laparoscopic US guidance	3-D forward viewing laparoscopes with Doppler and high frequency display	Boundary definition by endoscopic interrogation
Real-time updating of images Registration of fiducials Intraprocedural guidance	Display changes concurrent with therapy	Overlap of pre-op images on field	Correction of images for operative changes	Monitoring fudicials with <1 sec. correction of image/anatomy	"On-the-fly" updating of bulk/contour/shape of therapy, rendered in 3-D
Multimodal patient representation	Patient-specific longitudinal medical atlas	Individual serial images (US, CT, MR)	Digital representation from central image library	Regional correlation of morphologic (CT/MR) imaging Images accessible digitally	Total body image record accessible via holographic memory units in LAN, with fusion of images for longitudinal specific tissue characterization

TECHNOLOGY OBJECTIVE 2: ENHANCE AND EXPAND INNOVATIVE METHODS OF TISSUE RECONSTRUCTION AND ABLATION, PERMITTING REPAIR OR REMOVAL OF DISEASED TISSUE WITH THE LEAST TRAUMA TO THE PATIENT

Improve methods of tissue reconstruction and ablation

In conjunction with basic and clinical research into tissue characterization and signal processing, outlined above, parallel developments in tissue reconstruction, excision and ablation will be necessary to move minimal access surgery to the next plateau. Tissue excision implies the ability to repair the remaining tissues, with rejoining severed structures in a proper alignment, allowing healing to occur over time and maintaining the original integrity of the organ, even with small tubular structures such as the fallopian tube, ureter or coronary artery. Developments in these areas center around technologies to join tissues, provide adequate vision to the surgeon, and promote or inhibit biological functions to effect proper healing. For further details, please refer to Appendix B.

TECHNOLOGY OBJECTIVE 2: For innovative methods of tissue reconstruction and ablation, permit repair or removal of diseased tissue with the least trauma to the patient

Technical attribute that drives success for the object	Units of Metrics	Currently Available	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Tissue immobilization and adhesion	Luminal patency Wound healing	Rods, pins sutures, staples, metal stents	Improved stent design (cardiovascular) Paralysis/immobilization (<i>Botulinum</i> toxin)	Biodegradable stents Tissue glue/cement Depot drug bonded to stents	Refined adhesives with growth factors/inhibitors
Tissue orientation	mm of distraction • Degrees of alignment	2-D video-fluoroscopy	3-D video images • Real-time spiral CT	Video size and angle scale/measurement device • Fused real-time and pre-op images	Holographic real-time image • Frameless stereotaxy for non-CNS organs
Precise energy deposition	Tissue ablation • Functional preservation	Non-tissue specific delivery of energy	Tightly targeted energy deposition - better image guidance	Target specific ablation based on energy sensitizers i.e. immunophotodynamic therapy: • Better radio-sensitizers	Combined modality energy delivery to overcome heat sink effect • Differing tissue susceptibility in mosaic patterns of disease
Defining extent of ablation	Pathologic/normal tissue	Standard histologic evaluation of excised tissue	Optical coherence tomography of superficial lesions • Laser assessment of viability following tissue debridement	Reflectance spectroscopy via fiberoptics to characterize normal from abnormal tissue at ablation margins	"On-the-fly" cytologic margin assessment • Real-time imaging signal processing (see objective 1) without tissue removal
Improved hemostasis	Bloodless surgery	Mechanical, RF control of oozing small surface vessels	Ultrasonic tissue division refinements • Visualization of vessels before cutting intact tissue • Bipolar RF coagulation of 4 mm vessels	Identification of embedded blood vessels prior to division Vibration/accelerometer identification of cut vessels	Identification of actively bleeding vessel in a pool of blood via forward viewing doppler and occlusion with image guided glue/plug

TECHNOLOGY OBJECTIVE 3: DEVELOP METHODS TO ACCOMPLISH THERAPY USING THE LEAST INVASIVE ROUTE FEASIBLE, ALLOWING RAPID RECOVERY AND RETURN TO FUNCTION

A driver for all MIT is the prevention of pain and disability

The continuum of open surgery to laparoscopic surgery to endoluminal surgery to percutaneous surgery and subsequently transcutaneous therapy represents the full vision of the revolution of minimally invasive therapies. Fundamental roadblocks remain, particularly in the control of bleeding and delivery of energy (and drugs) to the appropriate site. A driver for all of MIT is prevention of pain and the disability caused by pain. The link between pharmacological advances in the field of anesthesia and technical advances in minimally invasive therapy is frequently overlooked but extremely important to the overall success of future therapies. For further details, please refer to Appendix B.

TECHNOLOGY OBJECTIVE 3: Accomplish therapy using the least invasive route feasible, allowing rapid recovery and return to function

Technical attribute that drives success for the object	Units of Metrics	Currently Available	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Percutaneous/transcutaneous device, drug and energy delivery	Minimal or no access chemotherapy/ablation	Skin patch or subdermal depot sources <ul style="list-style-type: none">• Luminal stenting	HIFU ablation of solid organ neoplasms <ul style="list-style-type: none">• Vascular stent-grafting	Degradable polymers with predictable drug kinetics <ul style="list-style-type: none">• Insertion of active micro carriers	Stimulated release of polymer bound drug <ul style="list-style-type: none">• HIFU “in situ” sculpting of lesion ablation• Percutaneous bypass surgery
Thermal-sensitive imaging	Precise energy deposition within target	US guided, cyro or RF ablation in solid organs	MR guidance of thermal energy deposition and characterization of effect	Thermal tissue cataloguing	US or CT guided thermal ablation
Miniaturization of current surgical devices	Size access port required	5 mm scopes and tools	2 mm tools 2 mm endoscopes with narrow field of view	2 mm endoscopes with improved optics Flexible, but sturdy 2 mm tools Larger tools which enter via 2 mm access port and expand	Tethered microrobotic tools Autonomous microrobots
Improved analgesia	Pain scale	Adequate superficial analgesia <ul style="list-style-type: none">• Visceral analgesia requires sedating drugs, i.e. propofol	Short acting systemic analgesic/anesthetics, i.e. remifentanyl	Specific systemic visceral sensory blockade with limited CNS effect	Organ specific visceral analgesia with post-procedural effect

TECHNOLOGY OBJECTIVE 4: DEVELOP A SYSTEM FOR PROSPECTIVE EDUCATION AND ASSESSMENT FOR THE INTRODUCTION OF NEW TECHNOLOGY AS A MEANS OF RAPIDLY DISSEMINATING NEW, EFFECTIVE MINIMALLY INVASIVE THERAPIES AND PREVENTING PREMATURE DISSEMINATION OF UNTESTED TREATMENTS

Training for new technology is needed to rapidly disseminate MIT

Since resources which provide health care are limited, new technologies should be carefully evaluated so that their efficacy and cost efficiency can be determined as rapidly as possible. This will require a standardized data collection system evaluated by an objective neutral health policy agency. Concurrently, the development of computer-based simulation for education, credentialing and certification will allow uniform national standards of technical expertise to be achieved. This advanced method of evaluation will rely upon developments in virtual reality simulation in the procedural medicine specialties and validation of skills acquisitions on simulators as equivalent to patient care experience. For further details, please refer to Appendix C.

TECHNOLOGY OBJECTIVE 4: Prospective education and assessment for the introduction of new technology, as a means of rapidly disseminating new, effective minimally invasive therapies and preventing premature dissemination of untested treatments

Technical attribute that drives success for the object	Units of Metrics	Currently Available	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Collect data on cost, quality of life, service	Relative costs	Limited individual studies	Insurer-based demographic studies	National assessments	Cost-effective application of inpatient/outpatient MIT's
Assessment by neutral party	Relative efficacy	Speciality sponsored review	Interdisciplinary review	NIH sponsored review	Independent technology assessment board
Simulation for education/ credentialing and certification	Nationally uniform standards of performance	Oral examination, case logs	Individual specialty simulations	Validation of simulation for education and skills acquisition	Acceptance of simulator training as equivalent to patient care in procedural specialties

TECHNOLOGY AND POLICY DRIVERS

Several key core technologies or “drivers” must be developed to enable breakthroughs to the next plateau in minimally invasive therapies. More detailed lists of needed technologies are provided in the appendices to support this section. Some of these drivers depend heavily upon computers to display images and precisely guide treatment. Underlying many of the concepts discussed below is a fundamental need for integration of developments in high powered computing and communication into medical care at every level. Computers by themselves cannot, and should not, replace compassion in the provision of medical care, but they can empower an individual physician. We believe that progress in reducing pain and suffering depends on a marriage between the computer and medicine. For an effective and efficient translation of silicon technology into biotechnology, a coordinated means of communication and technology transfer would be ideal.

Synergism of medicine and computer technology is necessary

POLICY DRIVERS

- ESTABLISH A SITE FOR SYNERGISTIC, INTERDISCIPLINARY COMMUNICATIONS AND RESEARCH WHICH WILL SERVE AS A “MEDICAL INCUBATOR” FOR TECHNOLOGY TRANSFER IN THE DEVELOPMENT OF NEW MINIMALLY INVASIVE THERAPIES

There is a crucial need for a central locus of research and development in effective minimally invasive therapies. This Center would serve as a site for coordinated development of image-guided, surgical and endoscopic therapies and would represent a forum where academia and industry could cooperatively develop technologies across intellectual and proprietary boundaries. Initially, this Center may represent a single, physical location accessible to the entire nation via the Internet. To take advantage of the intellectual efficiency which is afforded by proximity to other disciplines, it is suggested that this institute be located near a major medical or academic center where the infrastructure, personnel and intellectual property issues can be addressed most easily. Ideally, this institute would receive funding from government, corporate and academic sources, with corporate return on investment based upon royalty and licensing arrangements from procedures and devices which are developed at the center. The government return on investment is lower cost medical care resulting from shorter recovery times and a more rapid return to work, which minimally invasive therapies will produce.

Establish a Center for technology transfer

Technology evolution will support care at the most appropriate location

• OPTIMIZE THE DELIVERY OF THERAPY AT THE APPROPRIATE POINT OF CARE

As they are developed, MITs will initially be evaluated in central academic centers, with dissemination into the community and office setting as efficacy and safety are demonstrated. However, continued innovation is likely to occur in the central facilities. This evolution into a hub-and-spoke arrangement will allow care at the most appropriate location, whether office, clinic, community hospital or academic center. This evolution will extend across areas as diverse as hospital design and staffing, communications, and tool design. Appropriate coordination of this evolution is a policy requirement of this Roadmap. For further details, please refer to Appendix A.

TECHNOLOGY DRIVERS

Enhance distinction between health and disease

• DEVELOP TISSUE IDENTIFICATION AND CHARACTERIZATION AND MULTIMODAL IMAGE DISPLAY

The initial requirement for MIT is to identify disease within the body and characterize its relationship to surrounding structures. This driver focuses on imaging requirements to enhance distinctions between health and disease within the body and to represent those states in easily understood and manipulated formats for the treating physicians.

Develop methods of tissue reconstruction

• INNOVATIVE METHODS OF TISSUE RECONSTRUCTION

A major limitation to expanded application of MITs is the inability to control bleeding during surgery. Similarly, restoring and maintaining patency of obstructed tubular structures such as blood vessels, ureters, ducts and bronchi is necessary to preserve organ function. Until now, most MIT has been ablative or resective, i.e., organs are destroyed in situ or removed in toto. Methods of tissue reconstruction are necessary to expand surgical procedures done using MIT techniques. Lastly, display of the target tissue must be intuitive to the physician.

Optimize identification, visualization and susceptibility of target tissue

• INNOVATIVE METHODS OF TISSUE ABLATION

When tissue is most appropriately destroyed in situ, precisely controlled energy delivery can provide minimally invasive tissue ablation with limited collateral damage. Optimizing the identification, visualization and susceptibility of target tissues is the goal of this driver. This includes use of energy sources for ablation as well as deployment of bioactive polymers as drug delivery or structural elements.

• ACCOMPLISHING THERAPY USING THE LEAST INVASIVE ACCESS ROUTE FEASIBLE

Surgery has progressed from open exploration to videoscopic access and catheter-based delivery systems. Each of these techniques will continue to evolve and eventually be replaced, in some circumstances by totally noninvasive therapies. This driver uses developments in tissue access and image guidance to pursue noninvasive energy delivery, miniaturization of endoscopes, and least invasive therapies. Improvements in anesthetic, sedative and analgesic drugs will allow a comfortable transition of therapy from hospital-based care to outpatient settings.

Tissue access and image guidance developments will pace MIT

• PROSPECTIVE EDUCATION AND ASSESSMENT DURING THE INTRODUCTION OF NEW TECHNOLOGIES

As new technologies are developed, measurement of their effectiveness must be made, preferably by a neutral party. In this way, the early enthusiasm inherent in any new technique can be adequately assessed to prevent premature dissemination into common practice. Physicians must be adequately trained in techniques developed after the conclusion of their training, preferably without putting patients at risk during the early phase of the physician's learning curve. For this purpose, emphasis on computer-based training and simulation receives high priority, with virtual reality simulation of procedures encouraged as a method of medical education.

Training for new technology is necessary

CRITICAL INFRASTRUCTURE AND
CORE COMPETENCIES

The following table summarizes the list of key technologies and policy drivers and the infrastructure and core competency areas to which they relate.

KEY DRIVER	INFRASTRUCTURE	CORE COMPETENCY
Improved signal processing	<ul style="list-style-type: none">• MR• US	<ul style="list-style-type: none">• High speed computing• Signal algorithms
Image fusion	<ul style="list-style-type: none">• Imaging modalities• Image segmentation and registration	<ul style="list-style-type: none">• High speed computing• Real time volumetric display
Improved signal detection	<ul style="list-style-type: none">• Photon and other detectors	<ul style="list-style-type: none">• Algorithms• Sensors
Thermal sensitive imaging	<ul style="list-style-type: none">• MR• RF• HIFU• Lasers	<ul style="list-style-type: none">• Image processing & delivery systems
Molecular Probes	<ul style="list-style-type: none">• Biotechnology research establishment	<ul style="list-style-type: none">• Molecular biology• Physiology
Image guidance	<ul style="list-style-type: none">• Imaging• Real-time registration• Display technologies	<ul style="list-style-type: none">• Computing• Algorithms• Position tracking
Tissue reconstruction	<ul style="list-style-type: none">• Growth factors/inhibitors devices• Stents	<ul style="list-style-type: none">• Biochemistry• Metallurgy• Polymers
Tissue orientation	<ul style="list-style-type: none">• Video/fluoro	<ul style="list-style-type: none">• Image reconstruction
Precise energy delivery & defining extent of abltion	<ul style="list-style-type: none">• Various energy sources	<ul style="list-style-type: none">• “Identification friend/foe”• Selective susceptibility
Hemostasis	<ul style="list-style-type: none">• RF energy• Glues• Ultrasound• Laser	<ul style="list-style-type: none">• Vessel identification• Polymers• Image guidance
Access routes	<ul style="list-style-type: none">• Catheters• Endoscopes	<ul style="list-style-type: none">• Polymers• Mechanical engineering
Improved anesthesia	<ul style="list-style-type: none">• Pharmacology	<ul style="list-style-type: none">• Pharmacology
Prospective database	<ul style="list-style-type: none">• Standardized national data registry• Data collection system	<ul style="list-style-type: none">• Information systems
Neutral outcomes assessment	<ul style="list-style-type: none">• Government agencies• Employers insurers	<ul style="list-style-type: none">• Knowledgeable administrators• Standard data base
Simulation for education, training, credentialing	<ul style="list-style-type: none">• Specialty Boards	<ul style="list-style-type: none">• Computing• Virtual reality
Portable therapy	<ul style="list-style-type: none">• Provider education	<ul style="list-style-type: none">• Digital information• Telemedicine
Tool redesign	<ul style="list-style-type: none">• Manufacturers• Physician entrepreneur	<ul style="list-style-type: none">• Miniaturization• Micro-robotics

OPPORTUNITIES AND SHOWSTOPPERS

MIT is evolving rapidly

Minimally invasive therapy will continue to evolve at a rapid pace, driven by creative physicians, interested manufacturers and patients and payors who see medical care becoming less painful, easier, and faster. We are facing a revolution in medical care nearly as monumental as the advent of ether anesthesia was to the practice of humane surgery 150 years ago. Imaginative procedural specialists in surgery, medicine and radiology are developing innovative methods of treating diseases by importing the most appropriate enabling technologies from fields outside of medicine.

The global savings attributable to minimally invasive techniques, through shorter hospitalization, faster recovery, and more productive post-procedural recuperation should be a factor in the discussion of how research funds are invested in the future.

Virtual colonoscopy is an example of future MIT

The historical trend in medicine is for disease to be treated by open surgery when medical remedies fail. In the last 20 years, videoscopic and catheter-based procedures have supplanted many painful operations. In the future, totally noninvasive, image-guided procedures will replace some current minimally invasive procedures. An example of the next generation of MIT procedures is virtual colonoscopy. Within five years, painful and potentially hazardous screening colonoscopies may be replaced by a completely noninvasive imaging study.

Another example of future MIT is treatment of endocrine tumors

Another example is treatment of endocrine tumors of the pancreas. Current therapy requires open surgery to remove a portion of the pancreas containing the small tumor. Laparoscopic access currently allows the same procedure to be performed with smaller incisions, but it is often still necessary to remove pancreatic tissue. Further development of MIT methods could allow treatment by transcuteaneous, "incisionless" energy delivery using high intensity focused ultrasound (HIFU).

Stent grafts could also supplant open surgical by-pass grafts

Similarly, for the many patients who suffer from atherosclerosis, minimally invasive catheter-delivered vascular stent grafts could supplant open surgical bypass grafts of the major arteries, with later replacement of even this minimally invasive procedure by percutaneous delivery of plaque-inhibitory factors bound in polymers which coat the arterial walls.

a c r o n y m s

CABG	Coronary Artery Bypass Graft
CNS	Central Nervous System
CT	Computed Tomography
DARPA	Defense Advanced Research Projects Agency
ESWL	Extracorporeal Shock Wave Lithotripsy
HCFA	Health Care Financing Agency
HIFU	High Intensity Focused Ultrasound
IR	Infrared
LAN	Local Area Network
MIT	Minimally Invasive Therapy
MIS	Minimally Invasive Surgery
MR	Magnetic Resonance
NIH	National Institutes of Health
RF	Radio Frequency
US	Ultrasound
UV	Ultraviolet
VR	Virtual Reality

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The following appendices represent catalogues of necessary technologies for the specific driver cited in the preceding text.

APPENDIX A **FOR OPTIMIZING THE DELIVERY OF THERAPY AT THE** **APPROPRIATE POINT OF CARE**

Minimally invasive therapies should be provided at the appropriate point of care and dispersed to the widest possible medical practice setting which is consistent with good outcomes. Using a hub-and-spoke analogy, in some cases, the most appropriate location for minimally invasive therapies will be at the periphery of the spokes, at the community hospital or physician's office level. However, we do feel that there will be a realignment of the specialty expertise to regional centers of excellence (hubs) where the most advanced minimally invasive techniques will reside, taking advantage of expertise acquired through repetition and basic competencies of a team of interdisciplinary specialists.

On the other hand, the continued development of minimally invasive therapies means that procedures which previously required hospitalization will continue to be performed as outpatients and will eventually move to office based procedures for a large percentage of treatments which are currently rendered in hospitals. This should result in significant cost savings and also a restructuring of hospital design.

As new minimally invasive tools are developed, the ultimate design should incorporate cordless, self-powered, small, lightweight portable tools which can be integrated with telemedicine applications. They should be compatible with the wide variety of computer applications and mobile telecommunications which will be used for care delivery at sites remote from a central area.

APPENDIX B **DEVELOPMENTS ENHANCING INTERRELATIONSHIPS** **BETWEEN IMAGING AND TISSUE ABLATION AND** **MANIPULATION**

The technology represents a constellation of developments which serves to emphasize the interrelationship between Imaging (Technology Objective 1) and Tissue Access and Manipulation (Technology Objectives 2, 3, and 4). Briefly, these objectives will allow improved identification of disease, and then less traumatic treatment of it.

FIRST GRAND CHALLENGE: IDENTIFICATION

The first "Grand Challenge" deals with identifying areas of health and illness within the patient and emphasizes the fundamental axiom that in order to remove an abnormality, one must first find it and identify it in relation to its surroundings, thereby guiding the decision as to the most appropriate treatment. This core cluster of signal processing research and computer-aided visualization aims to provide information from currently used methods of imaging (US, CT, MR and nuclear medicine) combined with novel methods of tissue interrogation.

For instance, the development of tissue specific or disease specific injectable "molecular probes" will supplant the current use of radiologic contrast agents which relies on the binary function of whether or not an abnormality demonstrates increased blood flow compared to its surroundings. New agents will enable precise identification of sites of disease, margins with adjacent tissue and characteristics of growth. Visualization of pathologic change will be enhanced by optical methods of tissue identification, such as reflectance, fluorescence and IR/UV spectroscopy. Improved ligands for photosensitizers will make photodynamic therapy more tissue specific. Lastly, enthusiastic and intensive application of novel processing algorithms and computing to signal processing should provide methods of real-time, 3-dimensional

visualization and fusion of images to patient organs, providing intraprocedural navigation and guidance which will allow less invasive surgery on moving solid organs.

To develop image based methods of tissue identification, the following technologies are important:

- Improved signal processing
- Elaboration of image fusion methods
- Development of "molecular probes"
- Improved tissue recognition through spectroscopy and photodynamic agents
- Real-time updating of previously acquired images to reflect changes during therapy
- Automated segmentation
- Image/tissue registration for preprocedural and intraprocedural guidance
- "Tissue transparency" by tool-mounted imaging techniques such as ultrasound guided endoscopy and laparoscopy
- 3-dimensional display
- Eventual development of data-rich multimodal representations of patient specific anatomic displays (the "virtual patient") which will serve as individual longitudinal records of the state of health/disease at specific points in time

SECOND GRAND CHALLENGE: MINIMALLY INVASIVE TECHNIQUES **& TECHNOLOGIES**

The second "Grand Challenge" of enabling technologies concerns principally surgical techniques currently unavailable or in their infancy, permitting the move to the next plateau of surgery using minimally invasive techniques. This constellation will restore some of the dexterity and capabilities in videoscopic surgery that have been lost through minimal access ports. Improved tools will allow the extension of surgical dissection to areas which are currently difficult. In combination with in situ tissue ablation for those areas which cannot be removed and improved tissue reconstruction to repair areas where removal of tissue has occurred, the dexterity and flexibility of videoscopic surgery will reach a new level.

Specific emphasis is placed on integration of biocompatible, biodegradable polymer development for functional and structural elements during tissue reconstruction, as well as for pharmaceutical delivery agents to prevent the sequelae of tissue manipulation which result in the eventual failure of the surgical process (i.e. scarring or intimal hyperplasia).

For tissue ablation and reconstruction, the following technologies are important:

• *Improved Hemostasis Through Small Diameter Operative Ports*

Laparoscopic identification of vessels before they are cut is desirable, to prevent bleeding before it begins. Techniques such as laparoscopically-based doppler US, reflectance and IR spectroscopy, and vibration sensors are all feasible areas for development. Once a vessel has been cut, the site of bleeding must be identified and controlled quickly.

In that case, the use of laparoscopic doppler or accelerometer-based sensors could identify the bleeding site. Development of hemostatic methods such as HIFU, harmonic scalpels, tissue

sealants or glues, laser or RF coagulators can preserve a closed, bloodless field.

- *Dexterity Enhanced MIS*

Singularity free, 6 degrees of freedom dexterity enhancement includes position scaling, force scaling, tremor filtering, and gravity compensation.

Many systems proposed for robotic surgery are not singularity free and therefore not capable of natural motion for the surgeon.

- *Technologies for Tissue Immobilization and Adhesion*

Continued development of stents, both permanent and biodegradable, which can maintain patency of a narrowed tubular structure (vessel, duct, ureter, etc.) or serve as a scaffolding for healing tissue following excision or fracture. Novel methods of tissue immobilization such as botulinum toxin, which could provide temporary paralysis of an area during healing, should also be developed.

Tissue adhesives are needed to join or seal structures which eliminate the need for cumbersome suturing (in the case of soft tissues) or bulky fixation rods (for bone). This may be accomplished with laser welding or with bio-degradable polymers. The polymers may also serve as drug delivery vehicles to release growth factors (or inhibitors in the case of arteries in order to prevent restenosis).

Three-dimensional presentation of two-dimensional digital video images in order to facilitate proper orientation and alignment during tissue repair. In procedures which require “fused imaging,” the critical component is a real time, true volumetric display that can be viewed in a bright light environment.

- *Technologies for Precise Tissue Ablation*

Precisely targeted thermal methods of tissue destruction such as HIFU and radio frequency (RF) ablation which limit collateral damage to adjacent normal tissue should be developed.

To ensure complete destruction of targeted tissue, combination with sensitizing agents and alternative energy sources may be necessary (see below). Energy may be delivered via endoscopes, catheters, or in the case of HIFU or radiotherapy, transcutaneously.

- *Agents which render targeted (diseased) tissue more susceptible to damage than surrounding normal tissue*

This requires continued research into radio-sensitizing chemicals for enhanced radiation therapy and development of ligands for tissue-specific photodynamic therapy.

Photo-optical methods of tissue interrogation using spectroscopy or laser interrogation of tissue through fiber optic endoscopes, would allow on-the-fly biopsy and tissue characterization to guide extent of tissue ablation.

Development of injectable polymer-based depot drug sources, with predictable kinetics of drug release, or polymers which can serve as a nidus of stimulated release of drugs following transcutaneous application of energy sources (e.g., ultrasound) have applications in chronic conditions such as prolonged infection (e.g., tuberculosis, fungal disease) and cancer treatment.

To accomplish therapy using the least invasive access route which is feasible:

- *Percutaneous/Transcutaneous Drug, Device and Energy Delivery*

Tissue ablation using extracorporeal image-guided sources which can be delivered transcutaneously (e.g., HIFU and ESWL) will play an increasing role in ablative therapies but are limited

by the presence of bone and air along the pathway to the target tissue. Therefore, further development of delivery systems which provide routes around acoustic barriers are needed. Endoscopic access will likely continue to be used to treat hollow viscera. Tetherless robotic endoscopes may ultimately be more cost effective means of accessing intraluminal lesions. Catheter-based techniques which place vascular stent grafts across atherosclerotic and aneurysmal segments of major arteries will be expanded to other tubular structures.

- *Thermal Sensitive Imaging and Tissue Cataloguing*

Tissue ablation by thermal methods will initially require direct image guidance to monitor and control the deposition of energy into the desired target zone. At present, the best method of such guidance and control is magnetic resonance (MR) imaging. Further assessment of the role of MR-guided procedures is underway at several centers. However, it is possible to foresee a time when tissue thermal cataloguing has been done on MR units, and fixed quanta of energy can be delivered to targets using guidance methods other than MR. This will be especially important given the cost issues of the MR units as currently configured and the incompatibility of many medical instruments with the high magnetic fields surrounding the treatment zone.

- *Tool Miniaturization*

Progressive miniaturization of common surgical tools and endoscopes will allow reconstructive procedures to be performed through smaller access routes with less pain. Procedures will then occur in office or ambulatory settings.

- *Improved Anesthesia, Analgesia and Sedation*

Minimal and least invasive therapy relies in a fundamental way upon advances in the pharmacology of anesthesia, analgesia and sedation. Many current side effects of videoscopic surgery are related more to the control of pain and consciousness during the procedure than to the actual surgical intervention. Progress in short and ultrashort acting analgesics, sedatives and anesthetics will enhance the technological advances in procedural medical specialties.

**APPENDIX C
FOR PROSPECTIVE EDUCATION AND ASSESSMENT DURING
THE INTRODUCTION OF NEW TECHNOLOGIES:**

Collection of data on cost, quality of life and outcomes of service following minimally invasive procedures:

A real time standardized data set must be established which allows comparison to “standard therapy” which the new MIT seeks to replace.

This must include capital investment, depreciation costs, labor costs, standardized quality of life measurement before and after intervention and disability cost. These data must be assessed by some neutral party. Individual medical specialty boards may have conflicts of interest in assessing technology relevant to their own subspecialty, and thus a more global view might be obtained from the combined American Board of Medical Specialties or the National Institute of Medicine. Federal agencies such as HCFA and the NIH have generally been slow to respond to new technology and ill-equipped to evaluate it. We look to the *Performance Measurement and Outcomes Research Technology Roadmap* for guidance in this area.

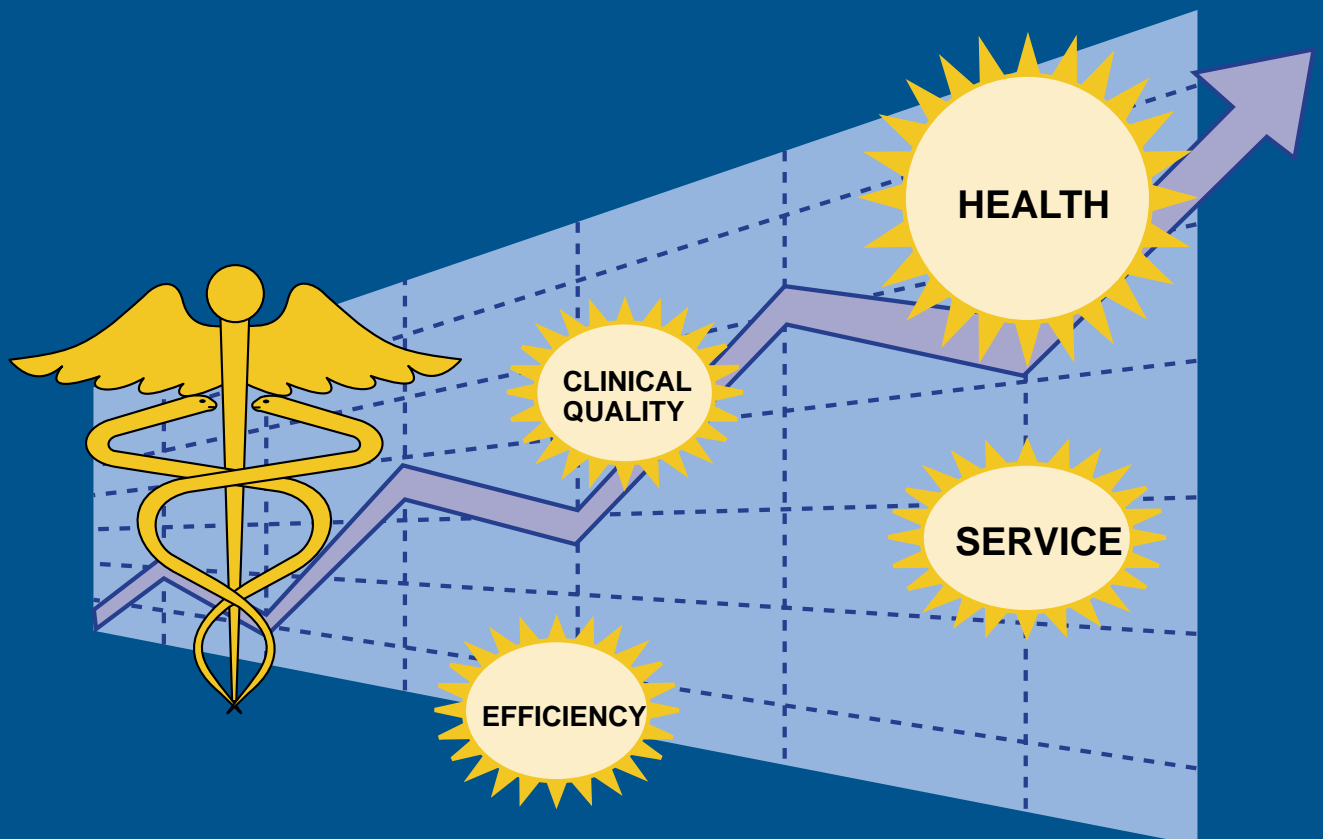
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a p p e n d i c e s

Education in new procedures can occur in part through various telemedicine initiatives. Computer-based education technologies such as virtual reality simulation of recently developed procedures will play a key role in training physicians. As part of the application of high powered computing and communication to medicine, the development of medical simulation should receive a high priority to allow education to occur without putting patients at risk. Realistic computer-based simulation can be used for initial training as well as for credentialing of physicians for hospital privileges and certification of procedural expertise.

PERFORMANCE MEASUREMENTS AND OUTCOMES RESEARCH TECHNOLOGY ROADMAP

The demand for performance measurement has increased dramatically with the insistence for accountability in health care. Current measurement efforts represent important first steps in what could prove to be one of the most important consumer information systems of the 21st century. Moreover, these performance measurement systems may provide efficient data sources to conduct outcomes research, the study of the effectiveness of health care interventions in clinical practice. This Roadmap addresses strategies for improving performance measurement and outcomes research for the nation's health care.



DESCRIPTION

Performance measurement and outcomes research are tools for evaluating health care quality and values

Performance measurement refers to the collection of data about clinical quality, efficiency, and service in health care. Outcomes research can be viewed as a specific type of performance measurement which focuses on measuring the effectiveness of health care interventions in clinical practice. Generally, outcomes research refers to the study of the processes and outcomes of health care interventions. In clinical trials outcomes research usually includes a broad range of clinical outcomes as well as quality of life outcomes and resource utilization. Outcomes research also refers to the study of the effectiveness of health care interventions in clinical practice, outside of controlled clinical trials. Performance measurement in general and outcomes research in particular are important tools for judging health care quality and health care value.

Such tools provide for performance improvements

Interest in measuring health care quality is increasing and stems from a variety of perspectives. For example, quality managers are interested in using the data to identify opportunities for performance improvement. Clinical and health services researchers are interested in using performance measurement data bases in outcomes research. In particular, as researchers face decreasing levels of research funding, they are increasingly using administrative data to study processes and outcomes of health care.

New measures better characterize processes and outcomes

Academicians are interested in defining, validating, and refining, new measures of quality to better characterize the key processes and outcomes of health care. Continued research activity in the development of new measures and in health services and outcomes research will ensure that evolving performance measurement systems provide clear and relevant information with which to inform health care operations and health care policy.

Consumers need more information to choose best value for health care

Consumers are also asking for more information to help them select among plans, providers, and among health care treatment options. The driving force behind the current interest in measuring health care quality, however, stems from purchasers' desire to measure value in health care. As health plans and providers compete for patients in the market place on the basis of cost of care, there is concern that quality of care may be compromised.

HEDIS represents the current state of the art in health plan performance

An appreciation of the current performance measurement systems and initiatives is necessary before the strategies for developing an ideal measurement system can be fully understood. The National Committee on Quality Assurance (NCQA) has developed the Health Plan Employer Data and Information Set (HEDIS). HEDIS represents the current state of the art in the systematic collection of

health plan performance information. It should be pointed out the HEDIS' focus is the health plan, which is only one component of the health care delivery system. HEDIS lacks important components of a performance measurement system such as a risk adjustment system. In addition, early versions of HEDIS have captured little information about health and functional status or clinical outcomes.

Version 3.0 of HEDIS promises improvements in this system. There will still be important logistical and financial issues to be worked out before all health plans can effectively participate in the HEDIS program. Measurement systems for hospitals, such as the Joint Commission on Accreditation of Health Care Organizations (JCAHO) Indicator Measurement System (IMS), provide opportunities for hospitals to compare performance with other institutions. Strategies for measuring performance in integrated health care delivery systems or networks are emerging from NCQA, JCAHO and others as the delivery systems evolve.

There are complementary efforts which focus less on data collection and dissemination and more on measurement development. The Agency for Health Care Policy and Research (AHCPR) has a new one-time funding solicitation entitled Expansion of Quality Measures (Q-SPAN), the goal of which is to fund consortia to develop and test new quality of care measures. Both the AHCPR and the JCAHO have developed catalogues, the Computerized Needs-oriented Quality Measurement System (CONQUEST) and the National Library of Health care Indicators (NLHI), respectively, that include a broad range of measures of health care quality for use in research, quality improvement, or accreditation.

Current systems have focused on traditional measures of health care quality and efficiency, which tend to be defined by providers rather than patients. The new Foundation for Accountability (FACCT) was developed in 1995 as a consumer and purchaser driven organization to promote a common set of patient-oriented measures of health care quality. AHCPR has funded a five-year project, The Consumer Assessments of Health Care Plans Study (CAHPS), to develop a survey instrument for helping consumers select high-quality health plans. These and other consumer-focused efforts should make the current versions of health care performance measurement more useful for patients. These efforts are primarily focused on patients who use health care services or who are enrolled in health plans or networks. True population-based performance measurement systems will require new strategies.

While these efforts represent important progress in the development of performance measurement systems, there is still much more to be done. Information systems need further development and data elements and indicators must be standardized. As health care systems focus on the care of populations and communities, demands for measurement will change. Whom to survey and what to

Other efforts complement HEDIS

Information systems must advance as well as standards for data and indicators

measure will differ from practices in traditional health care systems. Finally, as health care systems evolve, efforts to measure performance must be coordinated. Measurement at different levels of health care delivery can become redundant, expensive, and burdensome to patients and providers.

The goal of this Roadmap is to lay out a plan for developing and implementing a performance measurement and outcomes research information system for health care. The Roadmap which follows describes a systematic and incremental approach towards achieving this goal:

To develop and implement a dynamic, valid, reliable, comprehensive and cost-effective health care delivery performance measurement system. The system should include the measurement of health as well as the measurement of the quality of health care delivery.

TECHNOLOGY AND POLICY OBJECTIVES

The Roadmap describes the following objectives to be addressed over the next 15 years:

1. COLLECT DATA REQUIRED TO PRODUCE A CORE SET OF INDICATORS THAT MEANINGFULLY REFLECT HEALTH AND HEALTH CARE DELIVERY
2. INCORPORATE RISK ADJUSTMENT INTO THE MEASUREMENT SYSTEM
3. DISSEMINATE THE RESULTS AND ENCOURAGE CONTINUOUS PERFORMANCE IMPROVEMENT
4. COORDINATE NETWORK-WIDE MONITORING ACTIVITIES WITH REGIONAL AND NATIONAL ACTIVITIES
5. ANTICIPATE REQUIREMENTS FOR MEASUREMENT PERFORMANCE OF POPULATION-BASED HEALTH CARE SYSTEMS
6. DEVELOP A SYSTEM THAT IS RESPONSIVE TO THE EVOLVING ROLE OF PATIENTS IN THE HEALTH CARE DELIVERY SYSTEM

TECHNOLOGY AND POLICY ROADMAPS

OBJECTIVE 1: COLLECT DATA REQUIRED TO PRODUCE A CORE SET OF INDICATORS THAT MEANINGFULLY REFLECT HEALTH AND HEALTH CARE DELIVERY

This objective encompasses two important and interrelated goals:

- Determine the measures of interest
- Establish the means of collecting the measures

OBJECTIVE 1: Collect data required to produce a core set of indicators that meaningfully reflect health and health care delivery

Technical and/or policy attribute that drives success for this objective	Units of Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Develop inclusion and exclusion criteria for acceptance of indicators	Consortia representing public/private interests	Managed Care 30%, Medicaid, Medicare 15%	Expansion among all payers	Increased coordination across payers	Increased coordination
Define uniform data specifications	Consortia representing public/private interests	Efforts at DHHS	Build vendor capacity	Evolve coding systems and software capacity	Maturing but dynamic system
Ensure that a unique patient identifier is available for each member of the population	Consumer acceptance, legislative action	Multiple systems for patient identification	Develop data security/ confidentiality policies	Convert current systems	System-wide unique identifiers
Align incentives among constituents demanding performance measures	Link compensation for care delivery to high quality health care delivery and outcomes	Variable	Expand to more plans and systems	Expand degree of sophistication of measures	Maturing but dynamic system
Establish continuous quality improvement of data collection systems	Provider and plan acceptance, link QA to reimbursement	Variable	100% managed care, hospital 25%	Hospitals 50%	Part of core operations

In working towards achieving this objective, we should look to those organizations that are already active in the field of performance measurement, such as the NCQA and the JCAHO. Efforts to include measures that are relevant to diverse segments of the patient population will be important.

Version 3.0 of the HEDIS data set, which will include measures for the Medicare and Medicaid populations, represents unprecedented public-private cooperation in performance measurement activities. Efforts to include measures that are specifically relevant to individuals with chronic diseases will also be in demand. FACCT is in the process of developing condition-specific batteries of performance measures.

Because of the historical role that public entities, such as the US Department of Health and Human Services, have played in the establishment of a uniform data set, their knowledge and expertise will also be critical as these systems develop. There will be a need for legislative action and/or policies that allow use of unique patient identifiers while protecting patient confidentiality. Vendors will need to work closely with regulators and providers to develop products that will provide the technical solutions required to meet this objective.

Health systems will need technical advice on how to build on their current systems to develop information systems that efficiently collect, store, and analyze the data elements that are important for performance measurement. We should anticipate that community cooperatives or consortia will develop to promote coordinated efforts in local markets. The Cleveland Health Quality Choice initiative and others will serve as important models.

The health care system requires patient identifier and confidentiality policy/legislation

OBJECTIVE 2: INCORPORATE RISK ADJUSTMENT INTO THE MEASUREMENT SYSTEM

Risk adjustment is necessary for comparing provider plans

It will be critical to case-mix adjust or, more broadly, to risk adjust the measures in the core data set described in Objective 1, in order that meaningful comparisons among providers or plans can be made. Adjusting for risk is a complex task for several reasons. The strategies for case-mix adjustment vary with the measure or outcome of interest. The science of case-mix adjustment is evolving with alternative models coming forward, and there is lack of consensus on when to case-mix and what outcomes should be adjusted.

Systems exist for risk adjusting and must be evaluated

As with performance measurement broadly, many systems for risk adjusting exist and future efforts should begin with an evaluation of the state of the art systems. Systems for inpatient care and intensive care are more highly evolved than systems for outpatient care primarily because of the academic origins of the risk adjustment measures and because of the relative paucity of diagnostic information in the outpatient setting. Outpatient systems are becoming more problematic as reimbursement systems move toward capitation primarily because there may be less incentive to capture each and every encounter, lab test, referral and outcome. As the transformation toward capitation occurs, it will be important to align incentives so that providers are motivated to produce accurate and complete information about diagnoses, processes, and outcomes.

OBJECTIVE 2: Incorporate risk adjustment into the measurement system

Technical and/or policy attribute that drives success for this objective	Units of Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Identify data elements necessary for case-mix (risk) adjustment	Develop consortia with academic and operational representation	Variable models employed	Agree on basic strategies for major outcomes	Agree on strategies for secondary outcomes	Risk adjustment core data set established
Integrate into data collection	Integrate risk adjustment strategies into measurement	Variable strategies deployed	Agree on basic strategies for risk adjustment	Tailor strategies for different outcomes	Major outcomes adjusted
Develop guidelines for appropriate use of case-mix (risk) adjustment	Develop consortia with academic and operational representation	Link to reimbursement	Link to performance measurement	Establish use of ranking/profiling strategies	Routine use of risk adjustment

OBJECTIVE 3: DISSEMINATE THE RESULTS AND ENCOURAGE CONTINUOUS PERFORMANCE IMPROVEMENT

The data should be analyzed and the information disseminated in formats that are useful for the users. If the information does not facilitate consumer decision-making, if the information does not allow regulators to judge accountability, or if the information does not allow providers to scrutinize their own practices and improve those practices, the system will have fallen short of its goals. Therefore, careful planning and continuous feedback are critical as the data and information are being developed, piloted, and disseminated.

Over time, there should be measurable improvements in performance. Toward that end, providers must receive education in continuous quality improvement so that data can be screened, probed, and explored and responded to with plans for improving quality of care. Courses and texts describing techniques for continuous quality improvement and total quality management are increasing in number and physicians are increasingly being asked to champion quality improvement activities. Hopefully, these efforts will yield measurable improvement in performance.

Performance information requirements must be disseminated

Providers need to be educated to deliver measureable performance improvement

OBJECTIVE 3: Disseminate the results and encourage continuous performance improvement

Technical and/or policy attribute that drives success for this objective	Units of Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Define public's need for formats and frequency of measurement reports	Develop consumer consortia	Variable formats	Study current consumer initiatives	Develop alternatives formats	Increased use technologies
Define external needs for formats and frequency of measurement reports	Develop payer/regulator consortia	Variable formats	Study current formats	Develop alternatives formats	Increased use technologies
Define providers' needs for continuous quality improvement (CQI) activities	Develop clinical consortia	Variable formats	Study current alternatives	Develop alternatives formats	Evolving formats
Develop communications strategy for educating providers, consumers, employers, payers, and regulators about the value of CQI	Legislative action and policy to promote education	Basic education, set expectations	Continued feedback and education	Continued feedback and education	Ongoing consumer education

OBJECTIVE 4: COORDINATE LOCAL MONITORING ACTIVITIES WITH REGIONAL AND NATIONAL ACTIVITIES

Coordination of measurement will be an important component of performance measurement systems for two fundamental reasons:

- 1. Without coordination, it is difficult to ensure that comparable data are being collected
- 2. Without coordination, there will be unnecessary and wasteful duplication of effort

National and market forces will be necessary for coordination of performance measurements

Market forces will promote local and regional cooperation. National cooperation is less likely to take place in response to market forces alone. Whether national payers, such as the Health Care Financing Agency, will maintain a national quality assessment program in the long run is unclear. As Medicare beneficiaries enter managed care programs the task of monitoring performance becomes more challenging than it has been historically.

Public sector role in overall performance measure is being debated

The Physician Payment Review Commission is in the process of studying health plans' data capabilities and the feasibility of standardization across plans. The public sector's role in promoting coordination of measurement is under debate. The private sector's ability to promote competition is quite clear, but its ability to protect the public good is not. This will be one of the most controversial issues as performance measurement systems evolve in this competitive market place and will bear close observation as systems evolve.

OBJECTIVE 4: Coordinate local monitoring activities with regional and national activities

Technical and/or policy attribute that drives success for this objective	Units of Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Develop coordinated measurement efforts among local providers, plans, and networks	Community oversight, community partnerships	Evolution of partnerships	Establish measurement priorities	Measure and feedback	Collaborative CQI projects
Develop coordinated regional measurement efforts	Regional oversight – regional partnerships	Evolution of partnerships	Establish measurement priorities	Measure and feedback	Collaborative CQI projects
Develop coordinated regional/national measurement efforts	National coordinating body or system	Establish need and goals of effort	Evolve relationships	Prioritize measurement efforts	Measure and benchmark outcomes
Develop strategies for sharing the cost and burden of measurement across constituents	All of the above	Early dialogue	Revisit agreement	Continually reassess	Cost sharing models mature

OBJECTIVE 5: ANTICIPATE REQUIREMENTS FOR MEASURING PERFORMANCE OF POPULATION-BASED HEALTH CARE SYSTEMS

As health systems become responsible for covered lives under capitated reimbursement, there will be increasing interest in maintaining health of a specific population. Understanding the epidemiology of that population, including its demographic profile, disease profile, health care utilization patterns, public health problems, environmental risks, community resources and community values will be critical to planning for the health needs of the population. In particular, a comprehensive understanding of the impact of the health care system on the health and well-being of the community will require new relationships between health care providers, public health institutions, schools, and community health programs.

There will be an increasing need to understand health behaviors, health risks, reproductive health patterns, barriers to access, and prevalence of substance abuse and family violence. There also will also be an increasing need to gain access to public health data bases, cancer registries, and mortality records to more fully describe and monitor the health of populations.

A wide range of disease and demographic profiles are necessary to address health needs

OBJECTIVE 5: Anticipate requirements for measuring performance of population-based care systems

Technical and/or policy attribute that drives success for this objective	Units of Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Establish links between public health sectors', health plans', and providers' data systems	Community oversight, community partnerships	Begin dialogues	Demonstration projects	Evolving community systems	Evolving community systems
Develop population-based data repositories	Community oversight, community partnerships	Health plan-based data collection	Increased network-based data collection	Increased community-based programs	Widespread population-based
Develop incentives which encourage maintenance and improvement of population's health	Legislative action and policies	Early focus on prevention	Expand to high risk behaviors	Expand focus to wellness activities	Broad-based incentive program

OBJECTIVE 6: DEVELOP A SYSTEM THAT IS RESPONSIVE TO THE EVOLVING ROLE OF PATIENTS IN THE HEALTH CARE DELIVERY SYSTEM

There is growing evidence that increasing a patient's role in their own health care leads to improved care quality

There is growing evidence that patients' role in decision-making and in their own care leads to improved health care quality. In the decision-making domain, patients' preferences and values have been shown to be important determinants of whether certain procedures are appropriate. In addition, evidence shows that patients who are more active in their own care have better health outcomes than their passive counterparts.

Programs that promote self-care and patient decision-support should be deployed carefully and monitored closely. Not all proprietary programs are of high quality and not all patients are ready for collaborative relationships with their health care providers. There will be new demands for measures of quality of these programs as well as the level of involvement of patients in clinical decision-making and the effects on their care. Communication strategies for helping patients develop an appreciation for the value of being more active in their care will be important. Education of providers will be necessary as these programs become more widespread.

OBJECTIVE 6: Develop a system that is responsive to the evolving role of patients in the health care delivery system

Technical and/or policy attribute that drives success for this objective	Units of Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Develop systems for collecting important information from patients in a population or on enrollment in a health system	Community oversight, community partnerships	Variable intake enrollment	Standard health and risk assessment	Periodic updates	Ongoing iterative data collection
Develop systems capacity to support provider decision-support and continuing medical education for providers	Vendor and clinical alliances	Variable provider support	Computer decision-support	Continued deployment and expansion	Continued deployment and expansion
Develop communications strategies for promoting patient involvement in their care broadly	Policies and legislation action; community oversight	Begin dialogue with providers and patients	Encourage focused discussions	Broaden scope of collaboration	Continued deployment and expansion
Develop capacity to support and monitor the process and outcome of collaborative or shared decision-making	Vendor, clinical alliances	Little current activity	Plan collection around focused areas	Expand scope of data collection	Monitor process and outcomes

TECHNOLOGY AND POLICY DRIVERS

The three principal technology and policies that will drive the success of the above objectives are summarized below:

• ESTABLISH AN OVERSIGHT SYSTEM TO INITIATE AND MAINTAIN OBJECTIVITY OF THE HEALTH CARE DELIVERY SYSTEM AND TO PROTECT THE PUBLIC GOOD

Oversight will be essential to maintain the integrity of many key aspects of a performance measurement system. Such an entity or entities may exist in the public sector, in the private sector as a consortium with balanced representation, or as a public-private partnership.

The roles of this oversight body or bodies should be to oversee or audit data collection, analysis and reporting activities, oversee communications strategies, and coordinate with other oversight bodies to ensure standard approaches. In addition, these entities should develop policies for ensuring data security and confidentiality, and for sharing the cost of data collection, analysis, and reporting. These entities should also ensure that incentives are in place that promote the collection of accurate and meaningful data.

• GAIN CONSENSUS AMONG PROVIDERS, PAYERS, PATIENTS, AND HEALTH PLANS ON A CORE DATA SET OF PERFORMANCE MEASURES

While many of the fundamental building blocks of performance measurement systems exist, there is a need for integration, coordination, and evolution of individual components. As valid and reliable measures of health care quality are developed in academic centers, there is a need to integrate the use of these measures into operational environments. There should also be a process in place to allow for the evolution of the core data set over time. Researchers should be encouraged to participate in these consensus-building processes. Their input should ensure that data elements which are collected create useful outcomes research data bases.

• **DEVELOP AN OBJECTIVE AND EFFECTIVE COMMUNICATIONS STRATEGY TO PROMOTE A BETTER UNDERSTANDING OF THE GOALS, USEFULNESS, AND LIMITATIONS OF PERFORMANCE MEASUREMENT SYSTEMS**

The current demand for objective, comparable, and useful information about health care quality exceeds the U.S. health care system's current ability to provide such information. To prevent early abandonment of an initiative that will take time to fully develop, there is an urgent need for more widespread and compelling education about both the value and the limitation of performance measurement systems. Communication strategies should be developed for consumers, payers, providers, regulators, and policy makers alike.

CRITICAL INFRASTRUCTURE AND CORE COMPETENCIES

The following table summarizes the key drivers and the infrastructure and core competencies which will need to be achieved in order to develop a successful performance measurement program.

KEY DRIVERS	INFRASTRUCTURE/CORE COMPETENCIES
Establish an oversight system to initiate and maintain objectivity and protect the public good	<ul style="list-style-type: none">• Systems should be developed to promote objectivity and fairness in measurement, reporting, communications, and cost sharing• Progress in the market place at the community level should be monitored closely and a public sector role should be defined• Open-mindedness and close monitoring is critical during this 15 year period
Gain consensus among providers, payers, patients, and health plans on a core data set of performance measures	<ul style="list-style-type: none">• HEDIS 3.0 represents the state of the art in systematic measurment for health plans• The optimal measurement strategies for integrated health care delivery systems and the appropriate core data set for these entities will be complex.• Development of efficient and effective health information infrastructures will involve cooperation with vendors and careful planning with health care delivery systems
Develop an objective and effective communications strategy to promote a better understanding about the value and limitations of performance measurement systems	<ul style="list-style-type: none">• Expectations about performance measurement should be realistic• Patients should be educated about the value of performance information and benefit of being active in their own care• Providers should be educated about the use of performance measures in continuous quality improvement• Providers should be educated about the value of involving patients in their care

**Health information objectivity
and fairness is critical**

Maintaining objectivity and fairness and ensuring that the information is meaningful will be critical for performance systems to be truly helpful for all users. Whether objectivity and fairness in measurement can be maintained by the private sector alone and the role, if any, of the public sector, is unclear. Educating the public in how they can judge fairness in reporting will be important. There should be close monitoring of the process and a willingness to invoke a role for the public sector in protecting the public good. Open-mindedness is critical. In addition to monitoring fairness in reporting, such entities should establish policies for fairness in supporting the cost of data collection, analysis, and reporting. There is no room in the current US health care system for wasted or redundant use of resources.

**Measurement strategies
must be coordinated**

Measurement strategies are proliferating and there is need for some increased coordination and integration. Further cooperation will be needed to develop strategies for measurement at different levels of the health care system. Cooperation between measurement efforts will be necessary to allow for appropriate levels of measurement without redundancy.

A strategic communication program will be extremely important for success of performance measurement systems to educate the relevant parties about the value of performance systems, to set realistic expectations, and to help patients and providers move more effectively into collaborative relationships.

OPPORTUNITIES AND SHOWSTOPPERS

OPPORTUNITIES

- **THERE ARE IMMENSE OPPORTUNITIES FOR IMPROVING CONSUMERS' AND PURCHASERS' ACCESS TO IMPORTANT, RELEVANT, AND HELPFUL INFORMATION ABOUT THEIR HEALTH CARE**

Health care is one of the most critical purchases an individual can make and yet there is a dearth of information with which to make choices. If resources are deployed carefully, if planning is strategic, if expectations are realistic, there is great potential for dramatically improving the decision-support infrastructure in health care.

- **THERE ARE IMPORTANT OPPORTUNITIES FOR IMPROVING THE QUALITY OF HEALTH CARE BY USING PERFORMANCE MEASUREMENT INFORMATION IN CONTINUOUS QUALITY IMPROVEMENT ACTIVITIES**

If providers are equipped with the resources and skills necessary to perform continuous quality improvement activities, performance measurement systems should provide both opportunities to identify areas where improvement is necessary and provide a metric for monitoring performance improvement activities.

- **RESEARCH OPPORTUNITIES USING PERFORMANCE MEASUREMENT DATA BASES ARE ENORMOUS**

Research interests should be represented when data base structures and planning for performance measurement systems evolve. Health services researchers are currently exploiting administrative data bases. As data bases become more community based, quality can be monitored across the continuum of care. As clinical data sources become more sophisticated, there will be even more opportunities to capture clinically relevant information. Fostering research activities will improve the quality of the data bases and increase the value of the information gleaned from the data collection process. Planning for the needs of researchers will require their involvement early.

SHOWSTOPPERS

- **INCENTIVES NEED TO BE IN PLACE SO THAT DATA COLLECTION SUPPORTS QUALITY MEASUREMENT**

Administrative data sets have historically been very important in the data collection and measurement strategies for performance measurement systems. As electronic medical records develop and proliferate and as technologies to engage patients in their own care become more commonplace, there will be unprecedented opportunities to extract clinically relevant measures of process and outcome. The system should promote evolution from reliance on administrative data sources to the development of electronic clinical data bases.

- **EXPECTATIONS MUST BE REALISTIC**

If performance measurement systems are not well conceived or do not provide useful information, they will be abandoned. It will take time to develop robust systems. Therefore, expectations must be set appropriately.

- **COOPERATION, COORDINATION, AND OBJECTIVITY IS CRITICAL**

Coordination between providers, payers, plans, and researchers will be necessary to make the best use of these data collection efforts. Objectivity will be optimized with balanced representation in the planning and implementation of these performance measurement systems.

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g l o s s a r y

Case-Mix: The distribution of different characteristics, e.g., clinical, demographic, etc., within a group of patients.

Community-based Health Care: Refers to a health care delivery system that is responsible for providing services to a defined community.

Co-Morbidity: The number of clinical diagnoses or diseases which accompany a patient's main diagnosis or disease.

Continuum of Care: Includes all sites, including the home and community, in which care is rendered.

Continuous Quality Improvement: A technique for examining health care delivery systems with the aim of always looking towards improvement. Systems and processes, rather than individuals, are the object of the critique.

Data base: A system for storing data elements.

Data elements: An individual piece of information.

Health status: Refers specifically to the functional capacity of the patient, may be self-reported.

Indicator: A defined measure that is part of a measurement system.

Outcomes: The result of care. Outcomes may include clinical results, costs and resource use, and patient-reported quality of life or functional outcomes.

Population-Based Health Care: Refers to a health care delivery system that is responsible for providing services to a defined population.

Quality of Life Outcomes: The results of care as described in terms of the patient's functional capacity, functional impairment, etc., rather than described in clinical terms alone.

Risk-adjustment: A process by which a measure can be adjusted to account for differences in case-mix.

Severity of illness: The acuity and/or severity of a particular disease of diagnosis.

6

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PREVENTIVE MEDICINE AND INCENTIVE PROGRAMS TECHNOLOGY ROADMAP

The prevention paradigm offers tremendous opportunities for advancing the health and quality of life of individuals, communities and the nation. This Roadmap addresses the development of healthy communities by creating a prevention paradigm which motivates "healthy behavior."



DESCRIPTION

Health and prevention provide the best return on health care expenditures

A comprehensive prevention philosophy, reinforced by appropriate incentives, applied to individuals, health care systems, employers and communities provides the greatest potential for improving health. The World Health Organization (WHO) defines health as “a state of complete well-being, physical, social, and mental, and not merely the absence of disease or infirmity.” Health of individuals is inextricably linked to health of communities, and as such, cannot be viewed as simply the absence of disease, risk factors, or impaired performance. Focusing on health and prevention (as opposed to solely medical care and treatment) provides the best return on investment for our health care expenditures or health per unit cost.

The scope and terms “health,” “cost,” “prevention,” “preventive medicine,” “medical care” and “public health” are being redefined. While beyond the scope of this Roadmap, each of these terms and perspectives reflect the major historic and often counterproductive schism between individually based “clinical medicine” and population-based “public health.” Driven by the increasing scientific evidence of the effectiveness of prevention¹ and the fiscal imperative to control health care costs, both “clinical medicine” and “public health” are in the process of being reinvented. Outcome-oriented, vertically organized health care systems using capitation budgeting are moving to measure and improve their enrollees’ (population) health incorporating perspectives from both “medicine” and “public health.”

Preventive services are often more cost-effective than other medical practices

Public health departments, charged with monitoring and improving the health of populations using a fixed (i.e., capitated) budget, have theoretically weighed one health intervention versus another using quantitative methods such as epidemiology and cost-effectiveness analyses. With the exception of selected immunizations, the majority of clinical preventive services such as screening tests (e.g., pap smears, mammograms, etc.) and counseling to change behaviors have not been shown to save direct medical costs. However, they are at least as and often more cost-effective than other common medical practices.²

Employers recognize the value of saving indirect costs with decreased employee absenteeism

Similarly, the linkage between “health care costs” and other health care-related costs such as absenteeism, decreased productivity, and social dysfunction is being increasingly made by the private and public sector alike. Progressive employers have emphasized disease prevention and health promotion efforts, not because of the short term savings in direct medical care expenditures, but rather because of the more immediate savings in equally real indirect expenses recaptured through increased productivity and decreased absenteeism. The Panel on Cost-Effectiveness in Health and Medicine is a

national level expert group charged with assessing the state of the art of cost-effectiveness analysis for health and medical care. The Panel concluded that a societal perspective should be the standard approach used for economic study of health-related interventions.³

From the societal perspective, the reduction of the incidence and prevalence of disease through multiple strategies is the only long term means to control health care costs. Moving from treating disease to managing care, to managing disease, and to building healthy communities is not merely the “right thing to do,” but rather a fiscal imperative if society is not to consume an excessive proportion of its discretionary income on the health sector. A comprehensive prevention strategy uses primary, secondary and tertiary preventive strategies simultaneously.

Primary prevention is the best method to reduce health care needs and demand, rather than trying to diagnose and treat disease at an early stage. Primary prevention, as such, is the ultimate form of health care “demand management.” Secondary prevention, or the early detection of risk factors, is “case finding.” Tertiary prevention, the prevention of recurrence and complications in those already with disease, is “disease management.” All three approaches must be utilized in a prevention-oriented health care model.

Prevention, quality improvement, and accountability are integrally linked, and in a sense cofactors for a successful paradigm shift. A shared vision and strategic planning for the implementation of a comprehensive prevention paradigm are essential. This process will need to focus on the overall health of each community, identifying modifiable risk factors and determinants of health, intervening to reduce morbidity and mortality, and improve the quality of life and economic and social productivity. It will need to focus on the cultural, political, scientific and technological issues that both constrain and hold the greatest promise to promote this fundamental change.

The goal of this Biomedical Technology Roadmap (and eventually, of all health care systems):

To build healthy communities by creating a prevention paradigm which provides incentives for “healthy behavior” (e.g., individual, community, business and government) optimizing economic efficiency and productivity, health status, and quality of life.

Eight main areas are involved: Assessment, Behavior, Culture, Education, Health Care Delivery, Information, Marketing, and Physical Environment. Technology and policy can play a role in each of these and help make the transition to a prevention paradigm.

Primary, secondary and tertiary preventive strategies are used in a comprehensive prevention-oriented health care model

Stakeholders must share a vision and strategic plan to implement a comprehensive prevention paradigm

Eight main areas should be addressed in creating an effective prevention paradigm

TECHNOLOGY AND POLICY OBJECTIVES

The objectives over the next 15 years are the following:

- 1. IMPLEMENT POLICIES WHICH PROVIDE INCENTIVES TO PROMOTE INDIVIDUAL AND COMMUNITY HEALTH
- 2. DEPLOY A STANDARDIZED, ACCESSIBLE, EPIDEMIOLOGICALLY AND ECONOMICALLY BASED DATA SYSTEM TO FACILITATE REAL-TIME, EVIDENCE-BASED DECISIONS
- 3. DESIGN PERSONAL HEALTH INFORMATION SYSTEMS WHICH EMPOWER INDIVIDUAL DECISION MAKING
- 4. DEVELOP A NATIONAL RESEARCH PLAN THAT GIVES PRIORITY TO BUILDING HEALTHY COMMUNITIES
- 5. REORIENT HEALTH PROFESSIONS EDUCATION TO EMPHASIZE PRIMARY, SECONDARY AND TERTIARY PREVENTION

TECHNOLOGY AND POLICY ROADMAPS

A list of the requirements and drivers necessary to meet the objectives in the near (0-3 years), intermediate (3-6 years), and far (6-15 years) term are given in the following tables.

OBJECTIVE 1: IMPLEMENT POLICIES WHICH PROVIDE INCENTIVES TO PROMOTE INDIVIDUAL AND COMMUNITY HEALTH

The Objective 1 Table outlines the national policies and incentives that are critical to transition the country to the prevention paradigm. Incentives should be linked to outcome metrics and based on “Healthy People 2000” or similar objectives which reflect the overall health of the community. Such incentives would be made into “HEDIS-like” (i.e., Health Plan Employer and Data Information Set)⁴ indicators. Copays, coinsurance, and deductibles would be eliminated for prevention services and covered by every health plan in order to promote use. Personal incentives for healthy behavior would also be included. Healthy lifestyles would become the accepted norm and leading a healthy lifestyle would become more convenient than leading an unhealthy one.

Incentives include the elimination of copays and deductibles to promote individual and community health

OBJECTIVE 1: Implement policies which provide incentives to promote individual and community health

Technical and/or policy attribute that drives success of this objective	Units or Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Articulate political policy/will to reach goal incorporating incentive approach	National policy statement	None	≥1 Organization	> 25 organizations	Broad consensus
Obtain consensus on actionable core indicators for community health	Publication of “HEDIS-like” standards	None	1	Adoption by 25 public & private organizations	Universal adoption
Adopt laws, statutes, & policies that reward organizations for achieving objectives of community health	Laws & policies	None	No charge	75% Fortune 100 companies 50% federal agencies	Universal adoption
Increase accountability of decision makers & organizations using “at-risk” principles	% Orgs. placing resources at risk based on compliance with standards	None	<10%	50%	100%

OBJECTIVE 2: DEPLOY A STANDARDIZED, ACCESSIBLE, EPIDEMIOLOGICALLY AND ECONOMICALLY BASED DATA SYSTEM TO FACILITATE REAL-TIME, EVIDENCE-BASED DECISIONS

The data system is critical for the prevention paradigm

The Objective 2 Table describes the development of an epidemiologically and economically oriented information system as a critical technological requirement to facilitate the rapid movement toward a prevention paradigm in addressing the nation's health. Such an information system or information infrastructure would:

- Provide a description of the health of individuals as well as local, regional, state and federal communities
- Predict comprehensive health and economic costs associated with health status
- Provide for evidence-based decision support

Access and confidentiality must be addressed

The constant (and appropriate) tension between access to personal and community data and both individual and community security and confidentiality must be addressed initially and continually throughout the process of creating and linking data.

The information system should allow for trending and analysis down to the age, sex, and risk factor-

OBJECTIVE 2: Deploy a standardized, accessible, epidemiologically and economically based data system to facilitate real-time, evidence-based decisions

Technical and/or policy attribute that drives success of this objective	Units or Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Standardized population-based health risk factor survey	Survey	Fully: BRFSS in all 50 states	Reformulate & expand	Depoly, validate & modify	Deploy annually
Automated accessible & standardized patient medical records	Records	Development underway	Pilot testing	Initial deployment	Wide-spread adoption
Integrated population database of individualized records for surveillance needs	% population contained in system	Local fragmented	Pilot testing	10%	75-100%
Synthesized epidemiologic & economic models using standardized cost-effectiveness approach (Cost of illness model or quality of life)	Model	Fragmented, disease specific	Pilot testing	Initial deployment (purchasers)	Widespread adoption

specific levels to allow proper risk analysis and targeted interventions. It should include data on injury and illness and home, work and recreational events. Modified life-table analysis can then allow for specific forecasts of how each risk factor affects individuals' health and expected life span. The system should allow projections based on improving health of individuals and the community, including direct and indirect costs of prevention and intervention. Direct and indirect costs related to each disease and risk factor should also be computable on individual and community levels.

The system should be user-friendly, office based, and would require electronic access to some core aspects of medical records and health-related outcomes, for example, quality-adjusted life years, workdays lost or other measures of productivity. A computerized medical record, transferable between different health care systems, should outline risk factors, last risk update, required interventions due, and be able to generate reminders for appropriate care through utilization of a regularly applied, standardized population-based health risk factor survey such as an upgraded Behavioral Risk Factor Surveillance Survey (BRFSS)⁵.

In order to maximize payer and patient information, a corporate- or societal-level system should track clinics and providers by cost, access, quality, and outcomes, and provide real-time data on demographics and prevention efforts. This data ideally would empower individuals in their own quest for health and enable the utilization of individual risk factors. Key data elements, shown to be most important in describing the health of individuals and communities, would be derived from the definition of core indicators. These data sets would establish linkable sources which, when made appropriately secure, confidential and/or anonymous, would greatly advance the knowledge and incentives for prevention.

The data system should allow for comprehensive trending and analysis

A user-friendly system can outline risk, provide required interventions, and generate reminders

Access to the system will empower individuals

OBJECTIVE 3: DESIGN PERSONAL HEALTH CARE AND INFORMATION SYSTEMS
WHICH EMPOWER INDIVIDUAL DECISION MAKING

The Objective 3 Table outlines personal health care and information systems (PHCIS) to empower the individual with:

- Self care
- Uplink physiological, biochemical and visual data to a health provider
- Downlink individualized prevention and treatment plan from a health professional to the individual

OBJECTIVE 3: Design personal health care and information systems which empower individual decision making

Technical and/or policy attribute that drives success of this objective	Units or Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Consensus on data elements for personal health care and information systems (Home & community-based)	% population covered by standardized PHCIS	Fragmented nonstandardized	Pilot testing	Initial deployment 5-10%	Widespread 50%
Development of new technologies & infra-structure for self-care, physiologic monitoring & health systems interaction	Physiological monitoring hardware & software	Minimal fragmented	Pilot testing	Initial deployment	Widespread adoption

Technological advances, just like data systems development and integration, present potentially serious threats to the security and confidentiality of individuals and the health care provider-patient relationship. Nevertheless, advances in physiologic monitoring, telecommunications and scientific information will radically change the way in which health care, and particularly preventive care and information, is delivered. Electronically mediated home health care, to include nursing and routine follow-up physician visits, is possible. Nursing care would require the ability of the provider to activate the system to receive monitoring data at any hour.

Physiological control charts (e.g. pulse, blood pressure, oximetry) can also serve as an early warning indicator of a lack of homeostasis and trigger tertiary preventive interventions earlier. This individualized control chart can also prescreen safety sensitive occupations (e.g. pilots) prior to work. Home diagnostics, such as glucose, cholesterol, and hematocrit, body fat determinations, could also be linked to the automated patient record to improve patient care. The patient, by better monitoring of individual health status, would become a partner with the health care provider in creating optimal health.

Physiologic monitoring will radically change health care delivery

Physiologic control charts will allow care providers to partner with the patient

OBJECTIVE 4: DEVELOP A NATIONAL RESEARCH PLAN THAT GIVES PRIORITY TO BUILDING HEALTHY COMMUNITIES

A research plan can help identify critical communities and areas of health care

The Objective 4 Table outlines the national research plan needed to optimize prevention-oriented research in all aspects of an integrated health system and healthy community. Results could be assimilated into the epidemiologically and economically oriented model outlined in Objective 2. The plan would outline areas most promising and/or most in need of prevention research and highlight communities that could best support and benefit from the research. Clinical treatment research will be held to the same high outcome and cost-effectiveness standard that prevention has traditionally been held to. Innovative research methodologies need to be designed using individuals and communities to address prevention research questions, particularly in behavioral areas, in a timely fashion.

OBJECTIVE 4: Develop a national research plan that gives priority to building healthy communities

Technical and/or policy attribute that drives success of this objective	Units or Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Convene multi-sector national research conference to: 1) Prioritize research	Conference report	None	1	Update	Periodic update
2) Develop new research methodologies	Conference report	None	1	Update	Periodic update
Develop funding mechanisms for ongoing support of needs & deficiencies identified by the conference	% of research needs funded	NA	10-15%	15-50%	75-100%

OBJECTIVE 5: REORIENT HEALTH PROFESSIONS EDUCATION TO EMPHASIZE PRIMARY, SECONDARY, AND TERTIARY PREVENTION

The Objective 5 Table outlines health professions' education changes required to move to a prevention paradigm. The training would provide students with the broader definition of health and healthy communities and introduce them to the concepts of social, epidemiological, economic perspectives outlined in Objective Table 2. In order to adopt these perspectives, academic health centers must become accountable, in terms of health and economic outcomes, to and for the populations who partner (enroll) with them for their health and health care. Without placing institutions at risk, there is little likelihood for change.

Partnership with community organizations will not be a luxury but a necessity if health professions institutions are to optimize health. Accountability for patients and populations will drive an emphasis on quality improvement through prevention. Health professions institutions charged with improving the health of populations rather than simply delivering health care will begin to reunite medicine and public health in a new prevention paradigm in both academia and practice. Primary prevention linked with self-care using both individual and population-based approaches becomes comprehensive demand management. Similarly, medical care after illness becomes tertiary prevention or disease management using comprehensive approaches to minimize recurrence and complications in an epidemiologically oriented, cost-effective manner.

Students can be introduced to new health care concepts

Health professions must partner with community organizations to optimize health

OBJECTIVE 5: Reorient health professions education to emphasize primary, secondary, and tertiary prevention

Technical and/or policy attribute that drives success of this objective	Units or Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Encourage academic health centers to be primarily responsible for capitated enrolled populations	% responsible	Unknown	50%	75%	100%
Update & implement preventive medicine/ public health curriculum, incorporating individual & population-based epidemiological approach	% education programs teaching/implementing PPIP	Unknown	50%	75%	100%
Reform GME funding to an "all-payer" pool	Regulatory reform (HCFA)	None	Reform in place	Reform in place	Reform in place

*“Put Prevention Into Practice”
may be the indicator for
institutional commitment*

New emphasis will be placed on better definition of what is clinically and cost-effective for diagnostic, treatment and rehabilitative interventions — a standard which has been applied routinely to preventive interventions. By shifting graduate medical education funding to an “all-payer pool” (a truly societal perspective), purchasers of health care and educational institutions which provide care for them will have to incorporate changes in curriculum and practice. The “Put Prevention Into Practice” (PPIP)⁶ system of improving clinical preventive services may represent a sentinel indicator for institutional commitment to a prevention focus in the near term.

TECHNOLOGY AND POLICY DRIVERS

The principal technologies and policies that drive the success of the above objectives are:

- **CONSENSUS ON CORE (E.G., “HEDIS-LIKE”) INDICATORS OF COMMUNITY HEALTH**

This is a critical, early step in order to standardize and benchmark the current health of our communities and form the basis for evaluation on local, regional and national levels. These indicators should accurately reflect the accomplishment of prevention objectives in real time and form the basis of incentives programs. “Healthy People 2000”⁷ and the “Planned Approach to Community Health” (PATCH)⁸ represent excellent starting points for the creation of standardized core indicators.

*Consensus must form the basis for
evaluation of community health and
incentives programs*

- **NATIONAL POLICY STATEMENT AND EXPRESSION OF WILL TO ESTABLISH COMMUNITY HEALTH INCENTIVE PROGRAMS AS MAJOR PRIORITIES**

This is a critical initial step, placing health in the context of a true national priority both for its own sake and help the nation to remain economically competitive in the global marketplace. This should have wide political support in not only the public and private sectors, from the White House to state legislatures, to corporate boardrooms, and to private voluntary organizations.

*A priority for community health
will help the nation to remain
globally competitive*

- **DEVELOPMENT OF AN INTEGRATED EPIDEMIOLOGIC AND ECONOMIC MODEL TO EVALUATE PROGRAMS AND INITIATIVES USING A STANDARDIZED APPROACH**

This driver is critical to maximize the effect of prevention and incentive efforts. Interventions, therapies, programs and even status quo noninterventions in all aspects of health and health care (including empirical evidence from existing data systems) should be rigorously evaluated to assure they meet health objectives both epidemiologically and economically. Marginal, ineffective, or detrimental interventions can then be eliminated to improve health per unit cost.

*An integrated model will maximize
prevention and incentive efforts*

CRITICAL INFRASTRUCTURE AND
CORE COMPETENCIES

The following table summarizes the list of key technology and policy drivers and the infrastructure and core competency areas to which they relate.

KEY DRIVERS	INFRASTRUCTURE / CORE COMPETENCIES
Community HEDIS-like indicators	<ul style="list-style-type: none">• National consensus conference on standards• Publication of standards• National, state and private sector organizational acceptance of indicators• Medical record database for collection and analysis
National policy statement/will on goals/incentives	<ul style="list-style-type: none">• White House commission of public health, business, medical and political leaders• Marketing of goals/incentives approach to stakeholders• Adoption of goals/incentives by public health, business, medical and political organizations
Integrated epidemiologic/economic model	<ul style="list-style-type: none">• Standardization of cost-effectiveness model• Application of model to practice and research
Research prioritization conference	<ul style="list-style-type: none">• Develop new research methodologies• Prioritize health research• Fund research based on national priorities
Medical education reform	<ul style="list-style-type: none">• Reform GME funding to an “all-payer” pool• Revise curricula to epidemiological focus• Encourage academic health centers to capitate populations

There are a number of requirements necessary for switching to a preventive paradigm

The health care system must switch to a prevention paradigm to keep costs in check while improving the health of the entire nation. We must have robust, reliable, representative metrics that accurately reflect the current health of our population. These indicators should be standardized, distilled to a critical few by a national consensus conference. These indicators will require a standardized and accessible medical record database. The epidemiology and demographics of each community must be easily accessible, updatable, outcome oriented, and linked nationwide. This database must be the

basis for all health systems, public and private. It should be able to be aggregated and disaggregated for analysis at all levels.

A White House Conference would be useful to kick off an extended effort to define the will, vision and vectors to achieve a national commitment to a prevention paradigm based on appropriate incentives to build healthy communities. In order to have any chance for success, this will need to include non-health care related leaders, such as Fortune 100 Chief Executives, public and private educational institutions, etc. *A clear prevention policy statement must be credibly made and disseminated.* Without appropriate quantifiable and marketed incentives, any policy statement of intent is unlikely to have long term impact.

Development, trial, and deployment of an integrated epidemiologic and economic model is critical to ensure proper evaluation of interventions and noninterventions (usual practice). Research, as conducted today, does not follow a strategic vision or plan, and therefore has too much overlap and duplication, while not always having an epidemiological or when appropriate, economic focus.

All health professionals will need to become prevention oriented and trained at every stage of their education. Too often, medical education takes place in tertiary care centers, and the principles of capitation, at risk systems approach to medical practice, and outcomes-oriented, evidence-based quality improvement are never experienced. Curricula should be reviewed and modified to ensure that a well-taught prevention focus is present and that epidemiology and population focus is present in all stages of education.

1. High-level involvement

2. An economic model

3. Prevention-oriented education

OPPORTUNITIES AND SHOWSTOPPERS

Community involvement is necessary for the paradigm shift

• THE SWITCH TO A PREVENTION PARADIGM WILL REQUIRE SHIFTS IN CULTURE, VALUES, AND INCENTIVES

This is a wholesale shift from health care to health as the main focus and involves the entire community rather than just health care facilities and staff. The payback in preventing avoidable illness and injury will be tremendous. Special interests, which have benefited from over 50 years of indemnity, fee-for-service medicine not linked to community health, will be formidable in their potential resistance.

Prevention is the best means to reduce demand for service

• UNIFYING HEALTH POLICIES AND REIMBURSEMENTS ACROSS THE UNITED STATES AND ENSURING UNIVERSAL ACCESS IS A TREMENDOUS CHALLENGE

This will allow a long term focus on maintaining the health of individuals and communities, rather than avoiding short term outlays on an ever shifting population. Health insurance companies and other payers must see that prevention is the best way to ensure reduced demand for service.

It is necessary to promote appropriate healthy lifestyle practices

• IT IS EASIER TO LEAD AN UNHEALTHY LIFESTYLE. THERE ARE FEW INCENTIVES TO FOLLOW A HEALTHY LIFESTYLE OR TO PROMOTE A HEALTHY POPULATION

Marketing, education and policies will be key until the basic community infrastructure and culture change to make healthy behavior easy to obtain and the expected norm. Placing at risk resources and building systems which promote appropriate practices offer the best chance of reforming behavior and practice patterns by payers, providers, patients, and institutions.

Management is critical for clear, accurate prevention information

• PROVIDERS AND COMMUNITIES ARE OVERLOADED WITH INFORMATION DELIVERING CONFLICTING PREVENTION MESSAGES

Management of this information is critical both to the health staff and communities. The information must be filtered, analyzed, and summarized so that actions to improve health (broadly defined) per unit cost can be optimized.

• RESEARCH IS FRAGMENTED, OFTEN NOT OUTCOME OR PREVENTION ORIENTED, WITH LITTLE COST-EFFECTIVENESS ANALYSIS

A strategic plan for research and ensuring that cost and prevention are included in the planning and analysis of major studies is essential.

A strategic plan must accurately address cost and prevention

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glossary

Capitation: A system by which a company pays its medical care providers a set monthly fee for every subscriber assigned, or likely to be admitted, to their practices.

Health: From the World Health Organization: “a state of complete well-being, physical, social, and mental, and not merely the absence of disease or infirmity.”

acronyms

BRFSS	Behavioral Risk Factor Surveillance Survey
HEDIS	Health Plan Employer and Data Information Set
PATCH	Planned Approach to Community Health
PHCIS	Personal Health Care and Information Systems
PPIP	Put Prevention Into Practice
WHO	World Health Organization

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REHABILITATION SCIENCE AND ASSISTIVE TECHNOLOGIES TECHNOLOGY ROADMAP



Improvement in rehabilitative treatments and assistive technologies has great potential to improve the function of a large portion of our nation's population — persons with disabilities. More than 40 million Americans have one or more conditions that result in a limitation of life activities. Rehabilitative treatments and assistive technology opportunities are available to improve mobility, replace or enhance function by devices, and maintain function through treatment. This Technology and Policy Roadmap will focus the development and introduction of systems to restore or improve lost functional capability enabling meaningful life roles for persons with disabilities.

DESCRIPTION

Rehabilitation and assistive technologies are necessary to integrate persons with disabilities into society

The future health care system must better address the independence of and productivity of persons with disabilities

There is a critical need to advance the process of rehabilitation and the use of assistive technologies to augment lost function for the productive integration of persons with disabilities into society. Currently, there are more than 43 million Americans with disabilities. The national disability-related transfer payments and health care for disabled persons approach \$170 billion.¹

A significant part of the new emphasis on rehabilitation/assistive technology is a result of the success of America's health care system. The system's success metric, judged by the reduction of mortality, has, in turn, spawned an increasing incidence of chronic disabilities. The increasing numbers of persons with disabilities in all age categories are attributable to increased survivability of birth defects, trauma events, and acute or chronic disease. The future health care system must better address the quality of life issues of independence and productive achievement to reduce the costs of disabilities in this nation.

The goal of this Technology Roadmap:

To maximize the integration of society and the person with a disability by creating and restoring meaningful life roles through innovative rehabilitation sciences and assistive technologies.

Several areas will be emphasized to meet the goal, including:

- Interdisciplinary training and treatment
- Mobility improvement
- Outcomes assessment
- Information and education
- Physical environment modification

Technology and policy play an important role in each of these areas to assist the restoration of lost capabilities to the person with disabilities.

TECHNOLOGY AND POLICY OBJECTIVES

The objectives over the next 15 years are the following:

- 1. INCORPORATE INTERDISCIPLINARY REHABILITATION AND ASSISTIVE SERVICES AS A COMPONENT OF SHORT TERM MANAGED CARE TO REDUCE LONG-TERM SUPPORT COSTS AND IMPROVE OVERALL OUTCOMES**
- 2. DEVELOP INFORMATION SYSTEMS AND INFORMATION INFRASTRUCTURE TO ADDRESS REHABILITATION AND ASSISTIVE ISSUES, ASSESSMENTS, TRAINING AND TREATMENTS**
- 3. DEVELOP REHABILITATIVE TREATMENTS AND ASSISTIVE TECHNOLOGIES THAT ENABLE THE MOBILITY AND FUNCTIONAL CAPABILITIES OF PERSONS WITH DISABILITIES**

TECHNOLOGY AND POLICY ROADMAPS

A list of the requirements and drivers that are necessary to meet the objectives in the near (0 to 3 years), intermediate (3 to 6 years) and far (6 to 15 years) term is presented in the roadmaps that follow.

OBJECTIVE 1: INCORPORATE INTERDISCIPLINARY REHABILITATION AND ASSISTIVE SERVICES AS A COMPONENT OF MANAGED CARE TO REDUCE LONG-TERM SUPPORT COSTS AND IMPROVE OVERALL OUTCOMES

Future rehabilitive/assistive systems will require interdisciplinary treatment teams

Rehabilitation is a process that extends over various lengths of time and with various outcomes. It is becoming increasingly recognized that future advances in rehabilitation/assistive systems will require interdisciplinary treatment teams to overcome complex medical, psychosocial, and environmental barriers. These tightly functioning treatment teams will be composed of individuals trained in physical medicine, behavioral science, social science, the engineering disciplines, medical economics and public administration and policy to assist a person with disabilities address functional limitations in family, work, and community environments.

INTERDISCIPLINARY TREATMENT TEAMS

The traditional linear rehabilitation approach must change to a systems approach

A 1992 report published by the National Institutes of Health² cites the need for a systems approach as an essential feature of medical rehabilitation and ultimately all health care delivery. This report offers the replacement of the traditional linear rehabilitation process with a process incorporating interdisciplinary treatment teams.

The traditional linear rehabilitation process is conducted by a sequence of medical specialists and therapists services. In this linear, segmented process, there may be little overlap of observations and insights during this sequenced process with initial acute medical services. Conversely, by involving interdisciplinary teams addressing rehabilitation along with initial services, strategies for addressing the consequences of disabling conditions may be more effectively met.

REIMBURSEMENT SCHEDULE PILOTS

The systems approach will require specific fee scheduling for interdisciplinary treatment teams

In order to encourage the formation of these interdisciplinary teams, reimbursement schedules should be piloted for team-based approaches to treatment. Specific fee scheduling should be developed for candidate disease(s) or disorder(s) when an interdisciplinary approach has the potential to reduce

overall care and long-term support costs. The cost and outcome effectiveness of these teams and schedules may be evaluated over a period of time. Those pilots exhibiting cost and outcome effectiveness may be continued or even expanded. Further, the characteristics for “successful” (i.e., cost and outcome effective) interdisciplinary teams and services may be determined and used to guide further reimbursement schedule pilots.

OBJECTIVE 1: Incorporate interdisciplinary rehabilitation and assistive services as a compoent of managed care to reduce long term support costs and improve overall outcomes					
Technical and/or policy attribute that drives success for this objective	Units of Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Develop specific reimbursement schedules for cost effective, interdisciplinary team-based rehabilitation & assistive treatments that promote long term quality outcomes	Number of schedules	None	Incorporate pilot schedules for limited interdisciplinary care services addressing pervasive, cost intensive disease/disorders	Eliminate “unsuccessful” pilot schedules; address schedules for other areas Determine characteristics for successful interdisciplinary teams/ services	Eliminate remaining “unsuccessful” pilot schedules; address schedules for other areas
Establish national centers of excellence for interdisciplinary rehabilitation and assistive issues, training and treatment	Number of centers	None	3 Integrate medical & relevant sciences, engineering, skills training, etc. Incorporate rehab & assistive training in medical school cirriculums	6 Add additional disciplines if necessary	9 Comprehensive, coordinated analysis & response Virtual Center for interdisciplinary rehab and assistive
Develop Fellowships to encourage interdisciplinary participation	Number of National Fellows	None	15 Include persons with disabilities in research, training & treatment	30 Expanded disciplines integrated in research, training & treatment	45 Comprehensive disciplines integration in research, training & treatment
Federal/private sponsorship	\$M/\$M	None	100/50 Identify Federal resources to initiate cost & outcomes analysis for optimal rehab & assistive systems	125/175 Encourage public/ private participation in outcomes assessment	150/300 Expand partnerships & consortia to support cooperative technology utilization

*National centers for excellence
can be identified for R&D*

NATIONAL CENTER(S) FOR EXCELLENCE

Rehabilitation and assistive research and development (R&D) address a wide variety of topics. No single government agency or private organization is able to fund all important R&D areas. Thus, for the most effective use of the scarce rehabilitation and assistive system resources, national centers for excellence should be identified to perform rehabilitative and assistive research and development.

*Commercial participants
can incubate advances*

These centers of excellence must encourage commercial participation. Commercial champions should be identified to provide direction for applying research results. When coupled with effective, concurrent outcomes analysis of systems and procedures, these centers will serve as incubators for advances in rehabilitative and assistive systems.

*Alliances need to be formed to
advance and apply new technology*

COOPERATIVE TECHNOLOGY DEVELOPMENT

Much of this nation's current successful rehabilitation research is slow to gain broad utilization. Advanced, reliable, and affordable assistive products that are highly desired by persons with disabilities are often nonexistent or slow in achieving market acceptance. The assistive technology industry is dominated by several thousand small and micro companies (often less than 15 employees). These organizations typically have a narrow technical focus in addition to very limited funds to conduct research and development. Often technologies that support federal missions or mass consumer markets are available for inclusion into specialty equipment to support functional reaffirmation, but mechanisms to support cooperative technology utilization are underdeveloped.

As a result, alliances of manufacturers, insurers, research and government organizations should be formed to make more effective use of the limited resources. Further, rehabilitation and assistive stakeholders should be encouraged to coordinate the address of related issues, training and treatment. In particular, the more than 30 advocacy groups that currently receive public and private funding to address disabilities and disorders could serve to catalyze this integration effort.

**OBJECTIVE 2: DEVELOP INFORMATION SYSTEMS AND INFORMATION
INFRASTRUCTURE TO ADDRESS REHABILITATION AND ASSISTIVE
ISSUES, ASSESSMENTS, TRAINING AND TREATMENTS**

The development of information systems and a rehabilitation and assistive information infrastructure will advance the integration, delivery and effectiveness of therapies and devices. Information systems will be utilized to collect and disseminate information addressing a wide variety of applications including:

- Outcomes measurement, assessment and effectiveness studies
- Prevention and support education
- Behavior adaptation
- Device engineering and testing
- Delivery of services to the community and the underserved
- Patient records

among many others.

OUTCOMES EFFECTIVENESS TOOLS AND SYSTEMS

Currently, there is a lack of cost and outcome systems that address the entire context of the person with disability.

- Many managed care financial models focus on the reduction of care costs in the short term; length of stay (LOS), facilities, and the number of revisits are examples. *Financial models should be improved to address the long-term support costs of a person with disabilities* in addition to the short-term costs. Such a longitudinal view may have impact on the decisions made for short-term care.
- *Outcomes and effectiveness studies should be performed to evaluate the short- and long-term effectiveness of therapies and technologies.* Clinical trials should be conducted by representatives from the rehabilitation and relevant scientific and technologic disciplines to determine the optimal interventions for a variety of functional limitations.

Methods should be established of identifying and quantifying life-cycle hidden costs of nonintegration, such as secondary disabilities, more personal assistance services, and lost productivity. As noted in a recent article by Trachtman in *Assistive Technology*³, the cost of rehabilitation/assistive technology will not escape the broader national debate on health care reform and cost curtailment with the

*Financial models should address
the entire context of the person
with disability*

*Studies should be performed to
evaluate long and short-term
treatment*

*Identifying and quantifying hidden
costs for rehabilitation are necessary*

associated need for outcome studies. While the most obvious outcome measures are functional restoration, Trachtman points to the importance of goal-based outcomes. Goal-based outcomes can have firm economic bases focused on the individual life goals, weighted against real and actual assessment of the hidden costs of support.

PREVENTION OF DISABILITIES BY EDUCATION

Education can help prevent disabilities

The number of persons with disabilities is growing and can be attributed to a wide variety of factors. Health- and prevention-oriented lifestyles should be reinforced through education before incidence of disability, as well as emphasized during the cycles of medical and rehabilitation treatment.

Information systems should be developed for persons with disabilities

Prevention of impairments with long-term functional limitation consequences provides a person with greater individual independence. Correspondingly, with greater independence, an individual is less dependent upon society. Education and incentives can be facilitated by expanding information and media systems that effectively encourage the broader public to adopt healthy life styles. In addition, information systems (e.g., home-based media, information kiosks, etc.) should be developed to enable behavior adaptation of persons who suffer physical limitations in order to prevent secondary injury and health effects.

BEHAVIOR ADAPTATION

Improved models for assistive equipment and procedures are needed

The dominate factor in the reestablishment and integration of an individual into productive society is the self adaptation and learning of new behaviors. Often, full utilization is not achieved by users of assistive equipment and procedures because of specific behavioral traits. Improved models should be developed to quantify the behavior factors for well-being, adaptation versus maladaptation, and enhanced self care. These models may be used by the care professional (e.g., adaptation facilitators) to assist the person with disabilities in transitioning to healthy lifestyle traits.

OBJECTIVE 2: Develop information systems and infrastructure to address rehabilitation and assistive issues, assessments, training and treatments

Technical and/or policy attribute that drives success for this objective	Units of Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Perform collection & analysis of outcomes data to assess & measure rehabilitation assistive interventions	Diffusion of scientific-, financial-based outcomes & measures	Limited collection & analysis focused in specific areas	Selected data collection & analysis Propose & execute research protocols Develop prototype measurement tools Develop goal-based outcome measures	Collaborative data collection & analysis Development of standardized research protocols Develop new measurement tools Develop a consistent structure for hidden costs of non-integration	Wide-spread, coordination of collection & analysis Formalized research protocols Advanced measurement tools Develop long-term model of health care & rehabilitation costs & outcomes Establish quantifiable links and costs of secondary disability
Improved models for disabilities	Disability measures		Quantify measures for impairment Quantify prevalence of disability	Standardize measures of well-being Prototype models for disabilities	Formalized models for disability Establish long-term effectiveness of interventions during early childhood
Financial: Improved economic models for rehabilitation & assistive care Behavioral: Improved adaptation models for rehabilitation & assistive care	% of rehab costs covered	<5%	25% Quantify behavior factors for: - Adaptation - Maladaptation - Enhancing self care	50% Upgraded adaptation models	100% Formalized approaches for specific disability conditions
Prevention & education services, community based	Education & assistive systems	Non-integrated prevention & education	Community & home based media pilots Computer-aided, adaptive learning environments	Expanded multi-media systems (e.g., computer, TV, kiosk, etc.)	Prevention Orientation; Individual, family & care provider collaboration; Upgraded remote intervention Increased independence & responsibility for persons with disabilities

OBJECTIVE 3: DEVELOP REHABILITATIVE TREATMENTS AND ASSISTIVE TECHNOLOGIES THAT ENABLE THE MOBILITY AND FUNCTIONAL CAPABILITIES OF PERSONS WITH DISABILITIES

Taxonomies are being developed to identify and categorize disabilities

Taxonomies have been devised to deal with the extreme breadth of functional limitations ranging from physical disabilities, learning/emotional limitations, sensory deficits, and aging-related changes. Other taxonomies attempt to identify typical limiting characteristics of underlying disease or injury. *A National Institutes of Health (NIH) report⁴ notes that of the major causes of disability, approximately 93% involve one or more physical impairments.* Based on the National Health Interview Survey, which attempts to identify persons with activity limitations, the following list shows the general percentages of limitations resulting from all disease, injury, or congenital sources:

FUNCTIONAL CAPABILITY LIMITATIONS⁴

Mobility limitations	38%
Chronic diseases (respiratory, circulatory, cancer, diabetes)	32%
Sensory limitations	8%
Intellectual limitations (including mental retardation)	7%
Other	15%

Of the mobility limitations, orthopedic impairments and arthritis account for more than 28% of the cases.

Impaired functional capabilities force adaptation by the individual or the environment

Functional capabilities that are often impaired by a variety of the disease, injury, or congenital causes include mobility, communication, cognition, dexterity, manipulation, and environmental awareness. While these capabilities do not address specific activities of daily living, a limitation in one or more of these capabilities forces adaptation by the individual and/or the environment.

Limitations and integration vary with the number of factors

Each functional capability may have more or less importance depending on the position of a person in the life cycle, personal/family/social values, and degree of the impediment. For example, mobility and communication capabilities are very important to the early development of children with disabilities, whereas mobility and dexterity/manipulation can be more important to working age adults. Persons who experience disability early in life adapt to the challenges of their society and environment via a habilitation process. In this process, skills are developed at an early age allowing

an individual to function in society. Conversely, persons who are disabled later in life modify their skills via a rehabilitation process.

The following table addresses areas for improving the functional capabilities of persons with disabilities at the community, device development modeling and analysis, and example device (e.g., prosthetics) levels.

OBJECTIVE 3: Develop rehabilitative treatments and assistive technologies that enable the mobility and functional capabilities of persons with disabilities

Technical and/or policy attribute that drives success for this objective	Units of Metrics	Currently Deployed	Near Term (0 to 3 years)	Intermediate Term (3 to 6 years)	Far Term (6 to 15 years)
Integration of community based assistance & monitoring	Functional integration system	Sequential, problem driven intervention	Team-based, problem-driven intervention	Team-based, scheduled intervention	Full life cycle, continual team-based management
			Home based assistance & monitoring pilots	Expanded home information & assistive systems	Increased independence & responsibility for persons with disabilities
Development of improved movement models for device development		Independent models	Address patterns & causes of abnormal movement	Incorporate predictions for functional consequences of interventions	Development of advanced devices incorporating sensory feedback with substantially improved locomotion
			Characterize short- & long- term effects of sensory feedback, muscle stimulation & locomotion capacity	Characterize improved devices: reduced stresses & energy consumption; increased mobility	
Improve Prosthetics & Orthopedic Devices	Prosthetic interfaces	Silicon liners with distal pin	Development of suction suspensions	Develop polymeric interface prototypes	Advanced interfaces: elastic, compressive adjustable & cost effective
	Prosthetic feedback & control	Technology applications in wide range if disciplines	Prototypes: Integration of closed-loop feedback & sensory systems with powered orthoses	Advanced manufacture technologies to develop customized products at lower costs	Improved pseudo-autonomous gait, posture & stability for persons with disabilities Improved personal comfort & ambulation
Develop advanced micromachines & biomaterials to augment body components				Micromachines developed for neural signal extraction & control	Augmentation of muscle, ligament & skeletal structures with micromachine & biomaterial systems

TECHNOLOGY AND POLICY DRIVERS

A list summarizing the principal technologies and policies that will drive the success of the above objectives follows:

- **PROMOTE OUTCOMES STUDIES TO EVALUATE THE ENTIRE COST AND OUTCOMES CONTEXT OF THE PERSON WITH A DISABILITY**
- **DEVELOP SPECIFIC REIMBURSEMENT SCHEDULES FOR INTERDISCIPLINARY TEAM-BASED REHABILITATION AND ASSISTIVE TREATMENTS THAT PROMOTE LONG-TERM COST EFFECTIVENESS AND QUALITY OUTCOMES**
- **ESTABLISH NATIONAL CENTERS OF EXCELLENCE FOR INTERDISCIPLINARY REHABILITATION AND ASSISTIVE ISSUES, TRAINING AND TREATMENT**

CRITICAL INFRASTRUCTURE AND CORE COMPETENCIES

The following table summarizes the list of key technology and policy drivers and the infrastructure and core competency areas to which they relate.

KEY DRIVERS	INFRASTRUCTURE/CORE COMPETENCIES
Perform outcomes studies to evaluate the entire cost and outcomes context of the person with disability	<ul style="list-style-type: none">• Public and private payor organizations establish investment incentives for outcomes research• Collaborative collection and analysis of disability data• Information systems and information infrastructure to assess costs and outcomes• Formalized economic, outcomes and behavior models for disabilities
Develop specific reimbursement schedules for interdisciplinary team-based rehabilitation and assistive treatments that promote long term cost effectiveness and quality outcomes	<ul style="list-style-type: none">• Legislation identifying reimbursement schedule pilots for specific rehabilitative and assistive interventions• Updated financial models incorporating long-term (i.e., rehabilitative and assistive) support considerations as a function of care delivery• Integration of community-based assistance programs and monitoring systems to address wider spectrum of patient's lifestyle and encourage independence
Organize national centers of excellence to execute rehabilitation and assistive research, training and treatment	<ul style="list-style-type: none">• Cooperation among numerous disability advocacy organizations to pool limited resources• Coordinated, cooperative plan(s) for technology development and utilization• Multimedia tools emphasizing prevention of common disabilities• Incorporation of some rehabilitation and assistive care training in medical schools• Integration of a wide variety of scientific, engineering and economic disciplines to develop cost-effective, advanced devices with improved outcomes

OPPORTUNITIES AND SHOWSTOPPERS

OPPORTUNITIES

• DEMOGRAPHIC INCREASE IN THE US POPULATION OF THE ELDERLY

The elderly population in the United States has grown substantially in this century and will continue well into the next century. As people become older, the number of disabilities they suffer and the degree of functional limitation increase. As a result, rehabilitative and assistive treatments and systems will become an increasingly important component of the overall spectrum of health care and support in the nation.

An upcoming report, Sixty-Five Plus in the United States, supported by funding from the National Institute on Aging (NIA), expands on the information for the increased elderly population in the nation:

“America’s elderly population is now growing at a moderate pace. But not too far into the future, the growth will become rapid. So rapid, in fact, that by the middle of the next century, it might be completely inaccurate to think of ourselves as a Nation of the young: there could be more persons who are elderly (65 or over) than young (14 or younger)!

During the 20th century, the number of persons in the United States under age 65 has tripled. At the same time, the number aged 65 or over has jumped by a factor of 11! Consequently, the elderly, who comprised only 1 in every 25 Americans (3.1 million) in 1900, made up 1 in 8 (33.2 million) in 1994.

According to the Census Bureau’s “middle series” projections, the elderly population will more than double between now and the year 2050, to 80 million.

By that year, as many as 1 in 5 Americans could be elderly. Most of this growth should occur between 2010 and 2030, when the “baby boom” generation enters their elderly years.”⁵

With this expected increase in the elderly population of the United States, rehabilitative and assistive systems will become an increasingly important component of overall care. Such systems will enable greater individual independence and corresponding higher quality of life for individuals with disabilities.

Rehabilitation and assistive technologies will become increasingly important as America’s elderly population continues to increase

The US elderly population will more than double between now and the year 2050

• TECHNOLOGY OFFERS SOLUTIONS TO UPCOMING MAJOR CHANGES IN THE US HEALTH CARE SYSTEM

Significant changes in our health care system and support for persons with disabilities will be required in our society to provide an acceptable standard of living given the future demographics. Provision for reducing the prevalence and limitations of disabilities must be emphasized, both to the aging members and to those currently able bodied who place themselves at risk for injury or the onset of avoidable disease.

It is imperative that rehabilitation becomes an integral part of the full health provision system since preparing persons to reengage in productive life styles is now as important as acute care.

Provisions for rehabilitation and limitation of disabilities must be emphasized

SHOWSTOPPERS

• CURRENTLY, REHABILITATION IS NOT RECOGNIZED AS AN IMPORTANT COMPONENT OF THE OVERALL CARE SPECTRUM

Since rehabilitation is not recognized as a component of the overall spectrum of health care, the field has traditionally suffered from a lack of requisite resources (i.e., funding and trained specialists) and cooperative efforts. As stated in the NIH Research Plan for the National Center for Medical Rehabilitation Research:

“Medical rehabilitation research has not yet developed as a mature science because it has lacked a focus and an identity of its own. Inadequate funding of rehabilitation research, the lack of measurement tools, scant epidemiological data, and scarcity of well trained and productive rehabilitation scientists have contributed to the slow progress in improving rehabilitation for people with disabilities.”⁶

Currently, rehabilitaion is not a component of overall health care

• REHABILITATION AND ASSISTIVE RESEARCH EFFORTS ARE FRAGMENTED AMONG VARIOUS FEDERAL, STATE AND PRIVATE AGENCIES

Public and private sources to fund areas of rehabilitative and assistive research efforts are distributed among a number of organizations. Oftentimes, there is little coordination of efforts among these organizations to address the best overall utilization of these funds. As a result, rehabilitative and assistive research become duplicative rather than synergistic.

Public and private sectors must coordinate to develop a synergistic approach to rehabilitation and integration

In order to improve the lives of persons with disabilities, consortia (i.e., private sector) and advisory boards (i.e., public sector) must be organized to coordinate strategic research and development, training, and treatment planning.

Many medical and disability interventions have been driven by a “fix-it-at-any-cost” viewpoint at the expense of adaptation solutions that have the potential for increased cost-effectiveness while enabling a higher quality of life for the person with disabilities.

Adaptation should be emphasized when full restoration of functionality cannot be achieved

Full restoration may not be achievable for many medical, rehabilitation and assistive conditions. This fact should be appropriately emphasized with patients, care providers, and broader society. Solutions emphasizing adaptation, that incorporate environment modifications (e.g., physical, social, professional) with the implementation of rehabilitative and assistive equipment, will facilitate the reintegration of a person with disabilities into society. Such a view will enable the person a wider range of opportunities to be self-sustaining. This, in turn, should encourage the restoration of meaningful life roles for persons with disabilities.

Public awareness is essential for effective rehabilitation

It should be noted, however, that implementing these changes will require an effective public awareness effort. The compelling needs of the disabled, coupled with the cost and outcome merits of effective rehabilitation and assistive interventions, must be identified and articulated. The recommendations outlined in this Roadmap should be addressed to promote the adaptation perspective — such an effort will require effective organization, sufficient funding and broad based buy-in from rehabilitation and assistive stakeholders.

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Rehabilitation: The process by which physical, sensory and mental functional capacities are restored or developed after damage.

Rehabilitation Science: From the Institute of Medicine, National Academy of Sciences' description in the forthcoming report on assessing rehabilitation science and engineering, rehabilitation science is "the study of the fundamental, basic, and applied aspects of biology, medicine, and engineering as they relate to the restoration of functional capacity in a person, and the interaction of that person with the surrounding physical and social environment."

Assistive Technology: From the *Technology Related Assistance for Individuals with Disabilities Act of 1988 (Public Law 100-407)*, assistive technology is "any item, piece of equipment or product system, whether acquired commercially off the shelf, modified, or customized, that is used to increase, maintain or improve functional capabilities of individuals with disabilities."

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